

NATIONAL ORGAN TRANSPLANT ACT

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES
NINETY-EIGHTH CONGRESS

SECOND SESSION

ON

H.R. 4080

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO AUTHORIZE FINANCIAL ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS, AND FOR OTHER PURPOSES

FEBRUARY 9, 1984

Serial 98-64

Printed for the use of the Committee on Ways and Means



U.S. GOVERNMENT PRINTING OFFICE

WASHINGTON : 1984

34-347 O

H 781-49

COMMITTEE ON WAYS AND MEANS

DAN ROSTENKOWSKI, *Illinois, Chairman*

SAM M. GIBBONS, *Florida*
J. J. PICKLE, *Texas*
CHARLES B. RANGEL, *New York*
FORTNEY H. (PETE) STARK, *California*
JAMES R. JONES, *Oklahoma*
ANDY JACOBS, Jr., *Indiana*
HAROLD FORD, *Tennessee*
ED JENKINS, *Georgia*
RICHARD A. GEPHARDT, *Missouri*
THOMAS J. DOWNEY, *New York*
CECIL (CEC) HEFTTEL, *Hawaii*
WYCHE FOWLER, Jr., *Georgia*
FRANK J. GUARINI, *New Jersey*
JAMES M. SHANNON, *Massachusetts*
MARTY RUSSO, *Illinois*
DON J. PEASE, *Ohio*
KENT HANCE, *Texas*
ROBERT T. MATSUI, *California*
BERYL ANTHONY, Jr., *Arkansas*
RONNIE G. FLIPPO, *Alabama*
BYRON L. DORGAN, *North Dakota*
BARBARA B. KENNELLY, *Connecticut*

BARBER B. CONABLE, Jr., *New York*
JOHN J. DUNCAN, *Tennessee*
BILL ARCHER, *Texas*
GUY VANDER JAGT, *Michigan*
PHILIP M. CRANE, *Illinois*
BILL FRENZEL, *Minnesota*
JAMES G. MARTIN, *North Carolina*
RICHARD T. SCHULZE, *Pennsylvania*
BILL GRADISON, *Ohio*
W. HENSON MOORE, *Louisiana*
CARROLL A. CAMPBELL, Jr.,
South Carolina
WILLIAM M. THOMAS, *California*

JOHN J. SALMON, *Chief Counsel*

JOSEPH K. DOWLEY, *Assistant Chief Counsel*

ROBERT J. LEONARD, *Chief Tax Counsel*

A. L. SINGLETON, *Minority Chief of Staff*

SUBCOMMITTEE ON HEALTH

ANDY JACOBS, Jr., *Indiana, Chairman*

CHARLES B. RANGEL, *New York*
HAROLD FORD, *Tennessee*
JAMES M. SHANNON, *Massachusetts*
MARTY RUSSO, *Illinois*

W. HENSON MOORE, *Louisiana*
JOHN J. DUNCAN, *Tennessee*
JAMES G. MARTIN, *North Carolina*

PAUL C. RETTIG, *Professional Staff*
SANDRA K. CASBER, *Professional Staff*
DIANA C. JOST, *Professional Staff*
KAREN P. LLOYD, *Professional Staff*

CONTENTS

Press release of Friday, January 27, 1984, announcing the hearing	Page 1
H.R. 4080, text	3

WITNESSES

Department of Health and Human Services:	
Edward N. Brandt, Jr., M.D., Assistant Secretary for Health	37
Carolyn K. Davis, Ph.D., Administrator, Health Care Financing Administration	65
American Association of Tissue Banks, Robert E. Stevenson, Ph.D.	
American Liver Foundation, Gail Rempell	119
American Medical Association, James E. Davis, M.D., Leonard D. Fenninger, M.D., and Harry N. Peterson	111
American Society of Transplant Surgeons:	
Oscar Salvatierra, M.D.	86
Norman Shumway, M.D.	100
Thomas Starzl, M.D.	103
Barnes, Benjamin A., M.D., New England Organ Bank, Inc.	145
Davis, James E., M.D., American Medical Association	111
Eye Bank Association of America, A. H. Snyder, Jr.	131
Fenninger, Leonard D., M.D., American Medical Association	111
Gore, Hon. Albert, Jr., a Representative in Congress from the State of Tennessee	19
Heck, Ellen, University of Texas Health Science Center at Dallas	136
Karsten, Glen W., The Living Bank International	141
Living Bank International, Glen W. Karsten	141
Madigan, Hon. Edward R., a Representative in Congress from the State of Illinois	29
National Kidney Foundation, David A. Ogden, M.D.	124
New England Organ Bank, Inc., Benjamin A. Barnes, M.D.	145
North American Transplant Coordinator's Organization, Amy S. Peele	149
Ogden, David A., M.D., National Kidney Foundation	124
Peele, Amy S., North American Transplant Coordinator's Organization	149
Peterson, Harry N., American Medical Association	111
Rempell, Gail, American Liver Foundation	119
Salvatierra, Oscar, M.D., University of California at San Francisco, American Society of Transplant Surgeons	86
Shumway, Norman, M.D., Stanford University, American Society of Transplant Surgeons	100
Snyder, A. H., Jr., Eye Bank Association of America	131
Stanford University, Norman Shumway, M.D.	100
Starzl, Thomas, M.D., University of Pittsburgh, American Society of Transplant Surgeons	103
Stevenson, Robert E., Ph.D., American Association of Tissue Banks	130
University of California at San Francisco, Oscar Salvatierra, M.D.	86
University of Pittsburgh, Thomas Starzl, M.D.	103
University of Texas Health Science Center at Dallas, Ellen Heck	136
Walgren, Hon. Doug, a Representative in Congress from the State of Pennsylvania	31
Waxman, Hon. Henry A., a Representative in Congress from the State of California, and Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce	26

IV

SUBMISSIONS FOR THE RECORD

	Page
Abernathy, Y. T., Eye Bank Association of America, Southeast Region, letter ..	169
American Academy of Pediatrics, Paul F. Wehrle, M.D., letter.....	155
American Association of Nephrology Nurses and Technicians, Mary Baker, letter.....	158
American Burn Association, Charles R. Baxter, M.D., statement	138
American Council on Transplantation, Gary B. Friedlaender, M.D., letter and statement.....	158
Arizona Kidney Foundation, James F. Pfenning, letter.....	178
Baker, Mary, American Association of Nephrology Nurses and Technicians, letter.....	158
Baxter, Charles R., M.D., American Burn Association, statement	138
Blue Cross and Blue Shield Association, Mary Nell Lehnhard, letter and statement.....	164
Braine, Hayden G., M.D., Johns Hopkins Oncology Center, letter	171
Dobrovitz, Peter, Rochester, N.Y., statement	168
East Tennessee Eye Bank, David G. Gerkin, M.D., letter.....	34
Eye Bank Association of America, Southeast Region, Y. T. Abernathy, letter ...	169
Eye-Bank for Sight Restoration, Inc., Mary Jane O'Neill, statement	170
Friedlaender, Gary B., M.D., American Council on Transplantation, letter and statement.....	158
Gerkin, David G., M.D., East Tennessee Eye Bank, letter.....	34
Goldbeck, Willis B., Washington Business Group on Health, statement	175
Johns Hopkins Oncology Center:	
Hayden G. Braine, M.D., letter.....	171
Albert H. Owens, Jr., M.D., letter.....	170
Juvenile Diabetes Foundation International, Jason S. Roberts, letter	171
Lehnhard, Mary Nell, Blue Cross and Blue Shield Association, letter and statement	164
National Association of Patients on Hemodialysis and Transplantation, Inc., statement	173
O'Neill, Mary Jane, Eye-Bank for Sight Restoration, Inc., statement	170
Owens, Albert H., Jr., M.D., Johns Hopkins Oncology Center, letter	170
Pfenning, James F., Arizona Kidney Foundation, letter.....	178
Phoenix Transplant Center, Good Samaritan Medical Center, B. A. VanderWerf, M.D., Ph.D., letter.....	107
Roberts, Jason S., Juvenile Diabetes Foundation International, letter	171
VanderWerf, B. A., M.D., Ph.D., Phoenix Transplant Center, Good Samaritan Medical Center, letter	107
Washington Business Group on Health, Willis B. Goldbeck, statement.....	175
Wehrle, Paul F., M.D., American Academy of Pediatrics, letter.....	155

NATIONAL ORGAN TRANSPLANT ACT

THURSDAY, FEBRUARY 9, 1984

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, D.C.

The subcommittee met at 10:13 a.m., pursuant to notice, in room B-318, Rayburn House Office Building, Hon. Andy Jacobs, Jr. (chairman of the subcommittee) presiding.

[The press release announcing the hearing and a copy of the bill, H.R. 4080, follow:]

[Press release of Friday, January 27, 1984]

HON. ANDY JACOBS, JR. (D., IND.), CHAIRMAN, SUBCOMMITTEE ON HEALTH, COMMITTEE ON WAYS AND MEANS, ANNOUNCES A HEARING ON H.R. 4080, THE NATIONAL ORGAN TRANSPLANT ACT, TO BE HELD ON FEBRUARY 9, 1984

The Honorable Andy Jacobs, Jr. (D., Ind.), Chairman of the Subcommittee on Health of the Committee on Ways and Means, U.S. House of Representatives, announced today that the Subcommittee will hold a hearing on H.R. 4080, the National Organ Transplant Act. The hearing will be held on February 9, 1984, in Room B-318, Rayburn House Office Building, beginning at 10:00 a.m. H.R. 4080, introduced by the Honorable Albert Gore (D., Tenn.), was jointly referred to the Committees on Ways and Means and Energy and Commerce. The Committee on Energy and Commerce reported the bill with amendments on November 18, 1983.

BACKGROUND

H.R. 4080 would provide for the establishment of an assistance program for Organ Procurement Organizations (OPO's). Grants would be available for the planning, establishment, initial operation and expansion of qualified organ procurement organizations. Grant amounts of no more than \$4 million in 1984, \$8 million in 1985, \$12 million in 1986, and \$16 million in 1987, would be authorized from general revenues. A major part of the ongoing operational costs would be funded by the medicare end-stage renal disease (ESRD) program, as under existing law through payment of kidney acquisition costs.

A United States Transplantation Network (USTN) would be established under contract with the Department of Health and Human Services. The USTN would be a nationwide computer organ matching system and would have a 24-hour telephone hotline. The USTN would be funded by the medicare program. In addition, the USTN would operate a regional blood sera match system and would coordinate the transportation of donated organs.

The Public Health Service would be required to establish an office to administer grants to the OPO's and contracts with the USTN. In addition, this office would be responsible for the organ procurement activities of the ESRD program, which were previously under the Health Care Financing Administration. This office would coordinate Federal organ transplantation policies and programs.

The bill would provide for a scientific registry of patients who have received organ transplants. The registry is designed to collect data and the Department would be required to analyze this data and provide reports.

The bill would allow the Secretary to specify certain centers for transplant surgery and for other complex medical procedures. Only those designated centers

would receive reimbursement from medicare and medicaid for those designated complex procedures. Furthermore, the Secretary would be authorized to limit coverage of certain technologies and procedures. "If the patient, the person furnishing the technology or the procedure, and the conditions under which the technology or procedure is furnished meet such medical criteria of general applicability as the Secretary may specify."

The Secretary would be required to establish a task force on organ transplantation. The task force would conduct comprehensive examinations of the medical, legal, ethical, economic and social issues presented by human organ procurement and transplantation. In addition, the Secretary would be required to publish an annual report on the scientific and clinical status of organ transplantation.

The bill would authorize medicare coverage for outpatient self-administered immunosuppressive drugs (including cyclosporine) for medicare eligibles for the 36-month eligibility period following a transplant.

The bill would prohibit the purchase or sale of human organs, and also includes certain medicaid amendments relating to organ transplants.

DETAILS FOR SUBMISSION OF REQUESTS TO BE HEARD

Individuals and organizations interested in presenting oral testimony before the Subcommittee must submit their requests to be heard by telephone to Harriett Lawler ((202) 225-3627) no later than noon, Monday, February 6, 1984, to be followed by a formal written request to John J. Salmon, Chief Counsel, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. Notification to those scheduled to appear will be made by telephone as soon as possible after the filing deadline.

In order to assure the most productive use of the limited amount of time available to question witnesses, witnesses scheduled to appear before the Subcommittee are required to submit 100 copies of their prepared statement to the Main Committee office, Room 1102 Longworth House Office Building, at least 24 hours in advance of their scheduled appearance.

It is urged that persons and organizations having a common position make every effort to designate one spokesman to represent them in order for the Subcommittee to hear as many points of view as possible. Time for oral presentations will be strictly limited with the understanding that a more detailed statement may be included in the printed record of the hearing. This process will afford more time for members to question witnesses. In addition, witnesses may be grouped as panelists with strict time limitations for each panelist.

Each statement to be presented to the Subcommittee or any written statement submitted for the record must contain the following information:

1. The name, full address, and capacity in which the witness will appear (as well as a telephone number where he or his designated representative may be reached);
2. A list of any clients or persons, or any organization for whom the witness appears; and
3. A topical outline or summary of comments and recommendations.

For those who wish to file a written statement for the printed record of the hearing, six copies are required and may be submitted by the close of business Friday, February 24, 1984, to John J. Salmon, Chief Counsel, Committee on Ways and Means, U.S. House of Representatives, Room 1102 Longworth House Office Building, Washington, D.C. 20515. An additional supply of statements for the printed record may be furnished for distribution to the press and public if supplied to the Committee office before the hearing.

98TH CONGRESS
1ST SESSION

H. R. 4080

To amend the Public Health Service Act to authorize financial assistance for organ procurement organizations, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 5, 1983

Mr. GORE (for himself, Mr. WAXMAN, Mr. LUKEN, and Mr. SKEEN) introduced the following bill; which was referred jointly to the Committees on Energy and Commerce and Ways and Means

A BILL

To amend the Public Health Service Act to authorize financial assistance for organ procurement organizations, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "National Organ Trans-
4 plant Act".

5 TITLE 1—AMENDMENT TO PUBLIC HEALTH
6 SERVICE ACT

SEC. 101. Part H of title III of the Public Health Service Act is amended to read as follows:

1 "PART H—ORGAN TRANSPLANTS

2 "ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS

3 "SEC. 371. (a) The Secretary may make grants for the
4 planning, establishment, and initial operation of qualified
5 organ procurement organizations described in subsection (b)
6 and to expand the activities of such organizations.

7 "(b)(1) A qualified organ procurement organization for
8 which grants may be made under subsection (a) is an organi-
9 zation which, as determined by the National Center for
10 Organ Transplantation, will carry out the functions described
11 in paragraph (2) and—

12 "(A) is a nonprofit entity,

13 "(B) is not an organization which provides health
14 care services or carries out other activities not related
15 to the procurement of organs, except that it may be an
16 organization which provides health care services or
17 carries out other activities not related to the procure-
18 ment of organs if it was being reimbursed for organ
19 procurement activities under title XVIII of the Social
20 Security Act before the date of the enactment of this
21 part and establishes an advisory board as required by
22 subparagraph (G),

23 "(C) has accounting and other fiscal procedures
24 (as specified by the Secretary) necessary to assure the
25 fiscal stability of the organization,

1 “(D) has an agreement with the Secretary to be
2 reimbursed under title XVIII of the Social Security
3 Act for the procurement of kidneys,

4 “(E) has procedures to obtain payment for non-
5 renal organs provided to transplant centers,

6 “(F) has a defined service area which is a geo-
7 graphical area of sufficient size which will include at
8 least fifty potential organ donors each year and which
9 either includes an entire standard metropolitan statisti-
10 cal area (as specified by the Office of Management and
11 Budget) or does not include any part of such an area,
12 and

13 “(G)(i) in the case of an organization which is not
14 an organization which provides health care services or
15 carries out other activities not related to the procure-
16 ment of organs, has a Board of Directors which
17 includes—

18 “(I) members who represent hospital admin-
19 istrators, neurosurgeons or neurologists, intensive
20 care or emergency room nurses, tissue banks, and
21 voluntary health associations in its service area
22 and the general public residing in such area, and

23 “(II) from each transplant center in its serv-
24 ice area which has with the organization arrange-

1 ments described in paragraph (2)(G), a physician
2 who has practicing privileges in such center,

3 “(ii) in the case of an organization which is an or-
4 ganization which provides health care services or car-
5 ries out other activities not related to the procurement
6 of organs, establishes an advisory board for organ pro-
7 curement which will be an advisory board to its Board
8 of Directors, which will include the representation pre-
9 scribed by clause (i), which will have exclusive authori-
10 ty to establish policy for the procurement of organs and
11 the other functions described in paragraph (2), and
12 which will have no authority over any other activity of
13 the organization, and

14 “(H) has a full-time director and such other staff,
15 including the organ donation coordinators and organ
16 procurement specialists necessary to effectively obtain
17 organs from donors in its service area.

18 “(2) An organ procurement organization shall—

19 “(A) have effective agreements, to identify poten-
20 tial organ donors, with a substantial majority of the
21 hospitals and other health care entities in its service
22 area which have facilities for organ donations,

23 “(B) conduct systematic efforts, including profes-
24 sional education, to acquire organs and tissues from po-
25 tential donors.

1 “(C) arrange for the acquisition and preservation
2 of donated organs,

3 “(D) arrange for the appropriate tissue typing of
4 donated organs,

5 “(E) have a system to allocate donated organs
6 among transplant centers according to established
7 criteria,

8 “(F) provide for the transportation of donated
9 organs to transplant centers,

10 “(G) have arrangements to coordinate its activi-
11 ties with transplant centers in its service area,

12 “(H) participate in the United States Transplanta-
13 tion Network established under section 372,

14 “(I) have arrangements with tissue banks for the
15 preservation and storage of tissues as may be appropri-
16 ate, and

17 “(J) evaluate annually the effectiveness of the or-
18 ganization in acquiring potentially available organs.

19 “(c)(1) For grants under subsection (a) there are author-
20 ized to be appropriated \$5,000,000 for fiscal year 1984,
21 \$10,000,000 for fiscal year 1985, \$15,000,000 for fiscal year
22 1986, and \$20,000,000 for fiscal year 1987.

23 “(2) There are authorized to be appropriated for fiscal
24 years 1988 and 1989 such sums as may be necessary to con-
25 tinue grants for the initial operation or expansion of organ

1 procurement organizations which received initial grants for
2 such purpose under subsection (a) in fiscal year 1986 or
3 1987.

4 "UNITED STATES TRANSPLANTATION NETWORK

5 "SEC. 372. The Secretary shall by contract provide for
6 the establishment and operation of a United States Trans-
7 plantation Network which meets the requirements of subsec-
8 tion (b). The amount provided under such contract in any
9 fiscal year may not exceed \$2,000,000. Funds for such con-
10 tracts shall be made available from the Federal Hospital In-
11 surance Trust Fund established under title XVIII of the
12 Social Security Act.

13 "(b)(1) A United States Transplantation Network shall
14 carry out the functions described in paragraph (2) and shall—

15 "(A) be a private nonprofit entity which is not en-
16 gaged in any activity unrelated to organ procurement,
17 and

18 "(B) have a board of directors which includes rep-
19 resentatives of organ procurement organizations de-
20 scribed in section 371, transplant centers, voluntary
21 health associations, and the general public.

22 "(2) A United States Transplantation Network shall—

23 "(A) maintain a national registry of individuals
24 who need organs,

1 plication therefor has been submitted to, and approved by,
2 the Secretary. Such an application shall be in such form and
3 shall be submitted in such manner as the Secretary shall by
4 regulation prescribe.

5 “(b)(1) In considering applications for grants under sec-
6 tion 371, the Secretary shall give priority to any applicant
7 which has a formal agreement of cooperation with all trans-
8 plant centers in its proposed service area. The Secretary may
9 not make a grant for more than one organ procurement orga-
10 nization which will serve the same geographical area.

11 “(2) A grant for planning under section 371 may be
12 made for one year with respect to any organ procurement
13 organization and may not exceed \$100,000.

14 “(3) Grants under section 371 for the initial operation or
15 expansion of organ procurement organizations may be made
16 for three years. No such grant may exceed \$500,000 for any
17 year and no organ procurement organization may receive
18 more than \$1,000,000 for initial operation or expansion.

19 “(c)(1) The Secretary shall determine the amount of a
20 grant made under section 371. Payments under such grants
21 may be made in advance on the basis of estimates or by the
22 way of reimbursement, with necessary adjustments on ac-
23 count of underpayments or overpayments, and in such install-
24 ments and on such terms and conditions as the Secretary
25 finds necessary to carry out the purposes of such grants.

1 “(2)(A) Each recipient of a grant under section 371
2 shall keep such records as the Secretary shall prescribe, in-
3 cluding records which fully disclose the amount and disposi-
4 tion by such recipient of the proceeds of such grant, the total
5 cost of the undertaking in connection with which such grant
6 was made, and the amount of that portion of the cost of the
7 undertaking supplied by other sources, and such other
8 records as will facilitate an effective audit.

9 “(B) The Secretary and the Comptroller General of the
10 United States, or any of their duly authorized representa-
11 tives, shall have access for the purpose of audit and examina-
12 tion to any books, documents, papers, and records of the re-
13 cipient of a grant under section 371 that are pertinent to such
14 grant.

15 “(d) No organ procurement organization which receives
16 a grant under section 371 may use funds under such grant for
17 expenses for which reimbursement may be made under title
18 XVIII of the Social Security Act. No reimbursement of an
19 organ procurement organization under title XVIII of the
20 Social Security Act may be reduced because the organization
21 received a grant under section 371.

22 “(e) For purposes of this part:

23 “(1) The term ‘transplant center’ means a health
24 care facility in which transplants of organs are
25 performed.

1 “(2) The term ‘organ’ means the human kidney,
2 liver, heart, lung, pancreas, and any other human
3 organ or tissue (including corneas, bone, and skin) in-
4 cluded by the Secretary by regulation.

5 “ADMINISTRATION

6 “SEC. 374. (a) The Secretary shall establish in the
7 office of the Assistant Secretary for Health a National Center
8 for Organ Transplantation. The National Center shall—

9 “(1) administer this part and the organ procure-
10 ment activities under title XVIII of the Social Security
11 Act,

12 “(2) conduct a program of public information to
13 inform the public of the need for organ donations,

14 “(3) provide technical assistance to organ procure-
15 ment organizations receiving funds under section 371,
16 the United States Transplantation Network established
17 under section 372, and other entities in the health care
18 system involved in organ donations, procurement, and
19 transplants, and

20 “(4) issue an annual report on the status of organ
21 donation and coordination services and include in the
22 report an analysis of the efficiency and effectiveness of
23 the procurement and allocation of organs and a de-
24 scription of problems encountered in the procurement
25 and allocation of organs.

1 “(b)(1) The Secretary shall establish an advisory council
2 to advise the National Center. The advisory council shall
3 conduct comprehensive examinations of the medical, legal,
4 ethical, economic, and social issues presented by human
5 organ procurement and transplantation.

6 “(2) The advisory council shall be composed of fifteen
7 members appointed by the Secretary as follows:

8 “(A) Six members shall be appointed from physi-
9 cians who are eminent in the various specialties of
10 medicine related to human organ transplantation. Of
11 the physicians, at least three shall be transplant
12 surgeons.

13 “(B) Two members shall be appointed from indi-
14 viduals who are not physicians and who represent the
15 field of human organ procurement.

16 “(C) Four members shall be appointed from indi-
17 viduals who are not physicians or scientists and who as
18 a group have expertise in the fields of law, theology,
19 ethics, health care financing, and the social and behav-
20 ioral sciences.

21 “(D) Three members shall be appointed from indi-
22 viduals who are not physicians or scientists and who
23 are members of the general public.

24 No individual who is a full-time officer or employee of the
25 Federal Government may be appointed to the advisory coun-

1 cil. A vacancy in the advisory council shall be filled in the
2 manner in which the original appointment was made.

3 “(3) The advisory council shall, within eighteen months
4 of the date of the enactment of this part, conduct a national
5 conference to consider questions respecting—

6 “(A) the equitable access by patients to organ
7 transplantation,

8 “(B) the allocation of donated organs among
9 transplant centers and among patients equally medical-
10 ly qualified for an organ transplant, and

11 “(C) payment for nonrenal organ transplantation.
12 The Secretary shall publish the proceedings of the conference
13 within three months of its completion.

14 “(c) The Secretary shall provide for a registry of the
15 recipients of organ transplants. The registry shall include
16 such information respecting patients and transplant proce-
17 dures as the Secretary deems necessary to an ongoing evalu-
18 ation of the scientific and clinical status of organ
19 transplantation.

20 “REPORT

21 “SEC. 375. The Secretary shall publish an annual
22 report on the scientific and clinical status of organ transplan-
23 tation. The Secretary shall consult with the Director of the
24 National Institutes of Health and the Commissioner of the
25 Food and Drug Administration in the preparation of the

1 report. The Secretary shall make the report and other related
2 information available to service benefit plans, health insurers,
3 and other entities which are responsible for making payments
4 for health care.”.

5 TITLE II—MEDICARE AND MEDICAID

6 AMENDMENTS

7 SEC. 201. (a) Section 1862(a) of the Social Security Act
8 (42 U.S.C. 1395y(a)) is amended by adding at the end the
9 following new sentences: “The Secretary, after consultation
10 with the Assistant Secretary for Health, may determine that
11 items or services furnished with respect to a patient are ‘rea-
12 sonable and necessary’ for purposes of paragraph (1) only if
13 the patient, the person furnishing the items or services, and
14 the conditions under which the items or services are fur-
15 nished meet such medical criteria of general applicability as
16 the Secretary may specify. If the Secretary so determines
17 that payment for particular items or services will be made
18 only if furnished at a designated center or centers, payment
19 may be made under this title with respect to such items or
20 services at such a center only if the center agrees not to deny
21 a patient health care services on the grounds of race, color,
22 national origin, creed, source of payment for the items or
23 services, residence, or any other ground unrelated to the pa-
24 tient’s need for the item or service or the availability of the
25 item or service.”.

1 (b) Section 1886(a)(4) of such Act (42 U.S.C.
2 1395ww(a)(4)) is amended by adding at the end the following
3 new sentence: "Such term shall not include costs of organ
4 transplant procurement services."

5 SEC. 202. (a) Section 1902(a) of the Social Security Act
6 (42 U.S.C. 1396a(a)) is amended by striking out "and" at the
7 end of paragraph (43), by striking out the period at the end of
8 paragraph (44) and inserting in lieu thereof "; and", and by
9 inserting after paragraph (44) the following new paragraph:

10 "(45) provide—

11 "(A) for written policies respecting the cov-
12 erage under the plan of organ transplant proce-
13 dures, except that in the absence of such policies
14 the plan shall be deemed to provide for coverage
15 of such procedures in the same manner and under
16 the same conditions as such procedures are cov-
17 ered under title XVIII consistent with the second
18 and third sentences of section 1862(a), and

19 "(B) notwithstanding any other provision of
20 this title, that payment under the plan for such a
21 procedure shall be in the amount determined (with
22 respect to the diagnosis-related group described in
23 section 1886(d)(4)(A) including the procedure)
24 under section 1886 respecting payment for such
25 procedure."

1 (b) Section 1903(i) of such Act (42 U.S.C. 1396b(i)) is
2 amended by striking out the period at the end of paragraph
3 (6) and inserting in lieu thereof “; or” and by adding at the
4 end the following new paragraph:

5 “(7) with respect to any amount expended for an
6 organ transplant procedure for which the Secretary has
7 designated a specific center or centers for that proce-
8 dure under the second and third sentences of section
9 1862(a), if the procedure is not performed at such a
10 center.”.

11 (c)(1) Section 1902(a)(45)(A) of the Social Security Act
12 (added by the amendment made by subsection (a)) and section
13 1903(i)(7) of such Act (added by the amendment made by
14 subsection (b)) shall apply to a procedure performed more
15 than thirty days after the date the Secretary of Health and
16 Human Services establishes restrictions with respect to such
17 procedure under the second sentence of section 1862(a) of
18 such Act.

19 (2) Section 1902(a)(45)(B) of the Social Security Act
20 (added by the amendment made by subsection (a)) shall apply
21 to payment for procedures performed on or after the first cal-
22 endar quarter that begins more than sixty days after the date
23 of the enactment of this Act.

24 SEC. 203. Each hospital for which payment for organ
25 transplantation is made under title XVII or XIX of the

1 Social Security Act shall provide to the Secretary of Health
2 and Human Services for the registry under section 374(c) of
3 the Public Health Service Act information on all patients un-
4 dergoing organ transplantation in such hospital.

5 TITLE III—PROHIBITION OF ORGAN PURCHASES

6 SEC. 301. (a) It shall be unlawful for any person to
7 knowingly acquire, receive, or otherwise transfer any human
8 organ for valuable consideration if the transfer affects
9 commerce.

10 (b) Any person who violates subsection (a) shall be fined
11 not more than \$50,000 or imprisoned not more than five
12 years, or both.

13 (c) For purposes of subsection (a):

14 (1) The term "human organ" means the human
15 kidney, liver, heart, lung, pancreas, and any other
16 human organ or tissue (including corneas, bone, and
17 skin) included by the Secretary of Health and Human
18 Services by regulation.

19 (2) The term "valuable consideration" does not
20 include the reasonable costs associated with the remov-
21 al, storage, and transportation of a human organ.

22 (3) The term "commerce" means trade, traffic, or
23 transportation between a place in a State and any
24 place outside thereof or which affects such trade, traf-
25 fic, or transportation.

○

Chairman JACOBS. We are here to conduct our hearing today on H.R. 4080, the National Organ Transplant Act.

The first witness is our friend, Hon. Albert Gore, Jr., Member of Congress from the State of Tennessee. You are most welcome, sir. Please proceed in your own fashion.

I see that the first panel includes a lot of significant people, Hon. Henry A. Waxman, Member of Congress from California, chairman of the Subcommittee on Health and the Environment, Committee on Energy and Commerce; Hon. Edward R. Madigan, Member of Congress from Illinois, and Hon. Doug Walgren, Member of Congress from Pennsylvania.

Please proceed.

STATEMENT OF HON. ALBERT GORE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mr. GORE. Thank you very much, Mr. Chairman. I am greatly indebted to you and the members of the subcommittee for your courtesy in the scheduling of this hearing, and your courtesy in hearing us this morning.

I am also, obviously, greatly indebted to the chairman and ranking minority member of the Health and Environment Subcommittee, and my colleague from Pennsylvania, Mr. Walgren, as the sponsor of a key amendment for this legislation. I am very pleased to be here with them to discuss it.

H.R. 4080, the National Organ Transplant Act, is legislation designed to establish a national strategy to cope with the growing problems presented by the increasing need for transplantable organs.

I want to begin by saying how urgent the problems posed by this new and remarkable advance in health care technology are. I think that in order to understand, you have to look back just a few years at why this suddenly sprang up upon us the way it did.

For years, organ transplants were held back by the problem known as "rejection." You know that you have to have a very close match between the donor and the recipient. You may remember when Christian Barnard was transplanting hearts in South Africa, all of the news stories were about whether or not the recipient was going to reject the donated heart. That kept survival rates relatively low for a long period of time.

Then, a few years ago, there was a remarkable sudden advance in immunosuppressive drugs, one in particular called cyclosporine essentially solved most of the rejection problems that had been experienced in the past. All of a sudden, almost overnight, the survival rates jumped from the 20- and 30-percent range up into the 60- and 70-percent range. As a result, all of a sudden, there was a tremendous increase in the demand for transplantable organs.

There are thousands of Americans out there right now who are waiting for a transplantable organ, but our legal and societal structures haven't kept up with the advances in this technology.

Thomas Jefferson wrote a long time ago that "laws and institutions must move forward hand in hand with the progress of the human mind." The scientists and doctors have moved forward so rapidly here that our laws and institutions have yet to catch up.

Just one historic statistic that I think illustrates a big part of the problem. There are about 20,000 brain deaths in the United States each year. That tragedy is compounded by the fact that only about 2,200 of them result in organ donations and organ transplants.

There are so many Americans whose lives could be saved, and so many others whose quality of life could be dramatically enhanced that this opportunity must be seized. We can't allow it to become what Yogi Berra once described as an "insurmountable opportunity." We have got to advance our legal and social institutions in order to take advantage of it.

Before I go any further, let me clarify one issue that I believe has caused confusion for some people, and I think you will hear from some witnesses today who are concerned about this very point. The bill before you is a proposal to solve the problems posed by vital organ transplantation. This differs from tissue transplantation and the problems that are present with that technology. This point is critical to understand.

Over the years, two separate systems have developed, one for tissue retrieval and corneal, skin and bone transplantation, and another for vital organ retrieval and transplantation, which, until recently, has meant the end stage renal disease kidney system. Kidney transplantation is really where the vital organ transplant began in this country.

These two systems have developed quite apart from one another, which makes sense because the technical requirements in the two areas are really completely different. For example, while tissue retrieval takes place after the donor's heart has ceased beating and the body has been moved to the coroner's care, a vital organ donation requires that the dead body be maintained. This involves artificially continuing the heart beat, respiration, and many biochemical processes.

It also requires the patient to be kept in the intensive care unit after death. Finally, the removal of the organ is done in the operating room instead of the coroner's office. The universe of potential donors is so much smaller when you are talking about vital organs than it is with tissue that they are really two completely different problems.

Another important difference in the two systems is their origin and their source of funding. Tissue transplantation, and the system for retrieving tissue, have been in place for a long, long time. That system is supported by private and civic organizations, and it has functioned extremely well in meeting the demands in this field. Vital organ retrieval, on the other hand, has grown from the kidney retrieval program which is paid for entirely by the Federal Government.

I wanted to explain the difference between these two systems because where we have seen the problems and where we need to make changes is with the vital organ system, not the tissue system, and that is exactly what this legislation is aimed at.

It makes changes that will put in place the next generation system for vital organ retrieval. It does this by building upon the existing federally funded kidney retrieval program, and it does it in such a way that actual day-to-day operation of this system—this is a critical point, the actual day-to-day operation of this system

will remain in the hands of the private and voluntary groups that presently run that system. The bill does not create a federally run organ retrieval system, nor does it make any changes in the way that the tissue retrieval programs operate.

Now that I have tried to make it clear that the changes we are discussing are changes to improve the vital organ system, and not to try to fix the tissue system since the latter ain't broke, I would like to briefly mention the work of those individuals who are already involved in the organ system, and I do this because I believe that they are truly modern day heroes.

They save thousands of lives every year, and they have put this present system together on their own. I happen to think that they have almost worked miracles in making this thing work as well as it does, and I want to compliment them as do those Americans whose lives have been saved. They have truly done a magnificent job.

The present system for organ procurement and transplantation has gone about as far as we can expect it to go without a national focus and without more coordination at the national level. After all, we are already paying for it.

In 1983, we spent almost \$70 million for kidney retrieval. It ought to be better coordinated so that we can build more effectively upon the work of those who have put the system into place.

We don't want to replace the existing networks. What we really want to do is to get them to coordinate with each other better. You know, there are about 70 separate hospital-based systems and 37 independent-based systems out in the country.

One hundred and ten systems is a great many for this country. What this legislation is designed to do is to give incentives to those systems to do two things. First, establish closer ties with each other and with the U.S. Transplant Network that we want to establish at the national level, the computer registry, which again will be run by a private contractor. Second, the bill gives incentives to those regional networks to establish very close ties with the medical centers and the medical communities in their geographic regions.

In looking to solve these problems, we will hear from some who want to study the problem for a long time. But, Mr. Chairman, and members of the subcommittee, we have had enough studies. This thing has been studied and studied and studied, and the answers are in. We now know what needs to be done.

We have had some 5 days of investigative hearings on this topic in my subcommittee. Chairman Waxman has had many days of hearings in his subcommittee. Particularly, I want to mention Drs. Jeffrey Prottas and Roger Evans, who are under contract with the Health Care Financing Administration. Over the years, they have performed invaluable studies that we are indebted to in designing this bill.

The studies show that Americans are willing to donate. A recent Gallup poll survey shows that over 70 percent of those polled are willing to donate the organs of a loved one who has died. In fact, the recent rate of organ donations has been going up to record levels in the wake of publicity about the problem.

As Americans understand the opportunities to save lives, attitudes are changing dramatically. But there remains a very signifi-

cant problem in the organ procurement system nationwide. Many patients who would be ideal donors, and whose families are willing for them to become donors, are not being referred to the organ retrieval system. This can be traced to a need for more professional education of those members of the health care team who are best situated to make these referrals.

This legislation addresses this problem by providing incentives for organ procurement organization to have effective agreements to identify donors with the majority of the hospitals in their service area, and to conduct systematic efforts, including professional education, to acquire organs from potential donors.

Next, once a donor is identified, that donor has the potential not just to save one life, but to save many lives. But, unfortunately again, the present system is not designed to promote multiorgan procurement, and this has to be changed.

The small size of the donor pool for vital organs requires that there be maximum use of the organs from each willing donor. Once a donor has been identified and is in the system, there must be immediate access to one network that can quickly coordinate retrieval and placement of as many different organs and tissues as are available. There is presently not such a system.

There currently exists many different networks and valuable time is lost as transplant coordinators must contact different systems for placement of different organs.

We also must improve our system for allocating organs once they are retrieved. There presently is no medically agreed upon set of criteria for deciding where an organ should be sent once the decision is made to move that organ from the location where it was retrieved. These problems have resulted in the tragedy of many organs being wasted, and quite literally thrown away, while patients remain on waiting lists whose lives could have been saved by those organs that were thrown away.

The bill addresses both of these problems by establishing the U.S. Transplant Network. This privately run organization will serve to assist local organizations in matching retrieved organs with potential recipients. The framework is already operating and only needs to be completed. This system will also facilitate notification of tissue retrieval programs, enabling them to complete the maximum use of the donor.

Third, the availability of the organ transplant procedures themselves must be equitable. There are many lessons to be learned from the ESRD program. I will not elaborate on them here, but I will in my written statement. I will tell you in my written statement that this legislation addresses the problem of equity, I think, quite well.

One final point. This system that we are trying to put into place also addresses the problem of how we move experimental procedures into the mainstream of medical science.

At the current time, the Government and the private insurance companies are faced with a very difficult choice when a procedure that began as an experimental procedure advances and becomes able to save many lives. The people in the Government and the private insurance programs have to decide to reimburse it everywhere or nowhere.

For many years, the experts that have studied this problem, including the Public Health Services assessment of heart transplants in February 1980 and most recently the NIH Consensus Development Conference on Liver Transplants last summer, have all come to the conclusion that we ought to have a more controlled diffusion of once experimental technologies as they advance to the more widely available stage. This bill allows that to occur, and I am particularly indebted to Chairman Waxman for this provision.

Let me conclude by saying that the time to act is now. We have agreement on what the problems are, and on what the solutions are. We have the support of the transplant surgeons, the organ transplant coordinators, the organ procurement agencies, the Kidney Foundation, and many others. The list is very long.

We have spent literally hundreds of hours investigating the many issues involved here in drafting this bill. All of the key people involved in the effort toward retrieving organs and transplanting organs in this country have been closely involved in drafting this bill.

Mr. Chairman, we are on the verge of bringing this country into the future in dealing with this new era of organ transplantation. I appreciate your courtesy and I ask for your support of the legislation.

[The prepared statement follows:]

STATEMENT OF HON. ALBERT GORE, JR., A REPRESENTATIVE IN CONGRESS FROM THE
STATE OF TENNESSEE

Mr. Chairman, I am pleased to be here this morning as the Subcommittee on Health begins consideration of the bill H.R. 4080, the "National Organ Transplant Act," legislation to establish a national strategy to cope with the growing problems presented by the increasing need for transplantable organs.

I want to begin by saying how urgent the problems posed by this new and remarkable advance in health care technology are. And I would like to thank you for providing us with the opportunity to share with you the knowledge we have gained through the nine days of hearings we have had, and to help you understand and see the nature of the problems so that you may join with us to move quickly and expeditiously in solving these problems.

This problem is quite urgent for many thousands of Americans. We can deal with it as an issue, but for many thousands of Americans this is a life and death matter. I have constituents who are waiting right now, trying to get access to this life saving procedure, transplantation. Without it, there will be death; with it there will be life.

Before I go any further, let me clarify one issue that I know has caused confusion for some people. The bill before you is a proposal to solve the problems posed by vital organ transplantation. This differs from tissue transplantation and the problems that are present with the technology. This point is important to understand.

Over the years there has developed two separate systems, one for tissue retrieval and corneal, skin, and bone transplantation; and another for vital organ retrieval and transplantation, which until recently has meant the End Stage Renal Disease kidney system.

These two systems have developed quite apart from one another, which makes sense since the technical requirements of the two areas are quite different. For example, while tissue retrieval takes place after the donor's heart has ceased beating and the body has been moved to the coroner's care, vital organ donation requires that the dead body be maintained. This involves artificially continuing the heart beat, respiration, and many biochemical processes. It also requires the patient to be kept in the Intensive Care Unit long after death. Finally, the removal of the organs is done in the operating room instead of the coroner's office.

Another important difference in the two systems is their origin and source of funding. Tissue transplantation and the system for the retrieval of tissue have been in place many years. It is a system supported by private and civic organizations and has functioned well in meeting the demands of this field. Vital organ retrieval on

the other hand has grown from the kidney retrieval program, which is paid for entirely by the federal government.

I want to explain the difference between these two systems because where we have seen the most problems and where we need to make changes is with the vital organ system, not the tissue system. This is exactly what the legislation will do.

It makes changes that will put in place the "next generation" system for vital organ retrieval. It does this by building upon the existing federally funded kidney retrieval program, and it does it in such a way that actual day-to-day operation of the system will remain in the hands of the private and voluntary groups that now run that system. The bill does not create a federally run organ retrieval system, nor does it make any changes in the way the tissue retrieval programs operate.

Now that I have made it clear that the changes we are discussing today are changes to improve the vital organ system and not to try to fix the tissue system since "it ain't broke," I would like to briefly mention the work of those individuals already involved with vital organ transplantation.

The legislation supports and builds upon the work of the many individuals already involved in organ procurement. The people involved in this work today are modern day heroes. They save thousands of lives every year and have put this system together on their own. I happen to think that they have almost worked miracles in making this thing work as well as it does, and I want to compliment them, as do those Americans whose lives have been saved. They have done a magnificent job.

But, the present system has gone about as far as we can expect it to go without a national focus and without more coordination at a national level. We are paying for it. In 1983 we spent almost \$70 million for kidney retrieval. It ought to be paid for and coordinated so that we build upon the work that these people have done.

We do not want to replace these networks. What we really want to do is to provide incentives for them to do two things: one, establish closer ties with the medical centers and medical community in their geographic region, and two, encourage close ties with the United States Transplant Network that we want to establish at the national level.

In looking to solve these problems we will hear from some who want to study the problem a long time. We have had enough studies. We know what needs to be done.

I mentioned the lengthy investigative hearings that my subcommittee has held over the past year. In those hearings, and in the work we have done on the bill, we have all benefited from the extensive work that has already been done. I am referring specifically to the work of Drs. Jeffrey Prottas and Roger Evans, who over the past several years have thoroughly studied the systems of organ retrieval and transplantation under contract with the Health Care Financing Administration.

As a result of their work we are in the position to take immediate steps to correct shortcomings in the present system. This will mean many lives will be saved that would otherwise have been lost had we waited for further study. Furthermore, had we needed to wait for such a study, we would have to wait under the existing emotionally charged circumstances. Public interest and impatience would have undoubtedly resulted in a study of shorter duration under these significant pressures, and therefore, one that was less thorough and less comprehensive than the excellent work we have had the benefit of using in drafting H.R. 4080.

Although there is not time this morning to discuss all the things these studies revealed, I would like to mention a few very interesting points:

First, the studies show that except for the case of hearts, there is not a shortage of potential donors. Each year some 10,000 to 20,000 brain deaths occur. Unfortunately, this tragedy is compounded by the fact that only about 2,200 of these deaths result in organ donations and lifesaving transplants.

Americans are willing to donate. Recent surveys show that over 70 percent of those polled are willing to donate the organs of a loved one who has died. In fact, the recent rate of organ donations has been going up in the wake of the publicity about the problem. As Americans understand the opportunities to save lives, attitudes are changing, but there remains a very significant problem in the organ procurement system nationwide. Many patients who would be ideal donors and whose families are willing for them to become donors are not being referred into the organ retrieval system. This can be traced to a need for more professional education of those members of the health care team who are best situated to make these referrals.

The legislation addresses this problem by providing incentives for organ procurement organizations to have effective agreements, to identify donors, with a substantial majority of the hospitals in their service area and to conduct systematic efforts, including professional education to acquire organs from potential donors.

Second, once a donor is identified, that donor has the potential not just to save one life, but to save many lives. Unfortunately, the present system is not designed to promote multi-organ procurement. This must be changed. The small size of the donor pool requires that there is maximum use of the organs from each donor.

Once a donor has been identified and is "in the system," there needs to be immediate access to one network that can quickly coordinate retrieval and placement of as many different organs and tissue as are available. There is presently not such a system. There currently exists many different networks. Often valuable time is lost as transplant coordinators must contact different systems for placement of different organs.

We must also improve our system for allocating organs once they are retrieved. There presently does not exist a medically agreed upon set of criteria for deciding where an organ should be sent once the decision is made to move that organ from the location where it was retrieved. These problems have resulted in the tragedy of many organs being wasted while patients remain on waiting lists, many of whom will die before an organ becomes available.

The bill addresses both of these problems. By establishing the United States Transplant Network, this privately run organization will serve to assist local organ procurement organizations in matching retrieved organs with potential recipients. The framework is already operating and only needs to be completed. This system will also facilitate notification of tissue retrieval programs, enabling maximum use of the donor.

Third, the availability of the organ transplant procedures themselves must be equitable. There are many lessons to be learned from the ESRD program. One important lesson can be found in examining the patient mix prior to and after government involvement in this program.

In 1967, males outnumbered females 3 to 1, the patient population was predominantly white and college educated, and those over 55 only accounted for 7 percent of those being treated. In 1978, the male female ratio was 1 to 1, blacks now made up one third of the patients, and those over 55 accounted for 45 percent of the treatment population.

Two things happened to the patient mix once the government became involved in treating end-stage renal disease. First, the availability of care became more equitable. This is demonstrated by a patient mix that more closely parallels the incidence of kidney disease within the general population. Second, doctors abandoned the use of medical practice standards that were medically determined and had been in place prior to government intervention. In other words, patients who were once medically deemed unsuitable for this type of treatment were now being treated. Exactly what and how this happened raises some very difficult bioethical questions.

The legislation addresses these questions as well. First, by allowing the Secretary of the Department of Health and Human Services to limit reimbursement to selected centers and selected patients based solely on medical criteria, the bill stimulates a process that will assure equitable and timely access to new health care technologies such as organ transplantation. Second, this system will also insure the highest quality of care at the lowest possible cost, by restricting a procedure to a sufficient number of centers demonstrating excellence. Fewer centers allow more procedures to be done per center assuring adequate experience and benefiting from economies of scale. Finally such a system promotes the development of standards for care that can be more readily followed and adhered to.

These are only a few of the many issues the bill addresses, issues that must be addressed if we are to resolve the shortfalls of the present system. What is certain is the necessary information already exists from which sound policy can be developed in this critical area.

The time to act is now. We have agreement on what the problems are, and on what the solutions are. We have the support of the transplant surgeons, the organ transplant coordinators, the organ procurement agencies. We have spent hundreds of hours investigating the issues and in drafting the bill.

All of the key people involved in the effort toward retrieving organs and transplanting organs across the country have been involved in drafting this bill.

Mr. Chairman, we are now on the verge of bringing the country up-to-date in dealing with this new era of organ transplantation. Let us pass this bill quickly.

Thank you.

Chairman JACOBS. We appreciate your testimony, Congressman Gore.

Before we proceed, I understand some more chairs have arrived. I apologize for the participants here for the mismatch between the

room and the audience, but it is a little late to transplant the hearing to a larger room. Let's just pause a moment while the rustle takes place when they bring the chairs in.

We will proceed now with the chairman of our sister subcommittee in Commerce, Hon. Henry Waxman.

STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND CHAIRMAN, SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT, COMMITTEE ON ENERGY AND COMMERCE

Mr. WAXMAN. Thank you very much, Mr. Chairman and members of this very distinguished subcommittee. I appreciate this opportunity to testify and urge your support for the National Organ Transplant Act.

The legislation was reported by the Committee on Energy and Commerce on November 17, 1983, with broad bipartisan support.

In the past 20 years the transplantation of human kidneys has evolved from a state of clinical experimentation into a relatively routine surgical procedure.

Soon, I think, we will see the transplantation of human livers and hearts—for certain patients—become recognized as safe and effective surgical procedures, and I believe they too will become routine. Indeed, only last week, an advisory committee to California Blue Shield announced a decision to allow coverage of heart transplants for beneficiaries treated at the Stanford Medical Center.

But there is a gap between those in need of transplants and the availability of donated organs. As transplant technology becomes more sophisticated, this gap will widen.

The purpose of title I of H.R. 4080 is to increase the number of organs available for donation and to improve the process of matching donor organs with waiting recipients.

We amend the Public Health Service Act to authorize a program of grants for development and expansion of local organ procurement organizations.

In addition, the legislation provides for the development of a nationwide computer system to speed the matching of donor organs with waiting recipients.

The legislation would also provide for a scientific registry to facilitate long-term research leading to improvement in surgical procedures, patient selection and postoperative care.

Under H.R. 4080, organ donations will be increased and the matching process expedited without relying upon the sale of human organs. In fact, title III of the bill explicitly prohibits organ sales and imposes strict criminal penalties on those who would promote such practices.

In recent months, proposals have been made to encourage otherwise healthy individuals to sell one of their kidneys in exchange for payments ranging from \$6,000 to \$50,000. If these commercial ventures were allowed to proceed, I believe our efforts to promote voluntary organ donations would collapse, and health risks to transplant patients would greatly increase.

Human organs should not be treated like fenders in an auto junkyard.

Title II of the bill relates to medicare and is of interest to this committee.

Under current law, the Department of Health and Human Services must make specific decisions whether particular medical technologies will be reimbursed under medicare. The criteria used in making these decisions are whether the technology is "safe and effective, and not experimental."

In most cases, this decision process works reasonably well. The Department does not encounter problems when it can say with confidence that the technology is never safe and effective, or is to experimental for widespread use or, at the other extreme, that the technology is safe and effective for use by anyone at anytime.

However, as a given technology goes through various stages of acceptance and diffusion, a more sophisticated analysis is called for. Liver transplants and heart transplants are examples of two technologies that may be in that situation.

It doesn't seem proper for medicare to deny a needed and therapeutic procedure totally, because it is not yet clear whether it will be safe and effective across-the-board. On the other hand, it also seems inappropriate to make it available across-the-board when the risks of doing so are unknown or unresolved. Yet, according to testimony before our subcommittee, these two unsatisfactory choices are the only alternatives currently available to the Department.

Our bill would give the Department a third alternative. It would authorize the Secretary to place reasonable conditions or qualifications on medicare payments for a specific technology, to the extent justified by medical and scientific evidence.

Our bill does not require that the Department pay for transplants, or any other technology, nor does it prohibit payment. It simply gives the Secretary additional discretion to tailor the medicare coverage rules to the appropriate use of a particular technology.

Some people argue that our bill would inevitably result in broader medicare coverage and, therefore, greater outlays. I don't believe that this is true. There will be situations, such as organ transplants, where public pressure is mounting for medicare coverage. In the absence of the authority in our bill, the Secretary may not be able to avoid making an open-ended, across-the-board decision, but with this authority the Secretary could place reasonable, medically sound constraints on coverage which would, in turn, restrain outlays.

Before making such a limited coverage decision, the Secretary would have to consult with the Assistant Secretary for Health who in turn would customarily consult the NIH, the medical speciality societies, and other scientific and medical experts.

This is a very important improvement in the medicare program, designed to make it more responsive to the needs of its beneficiaries and more flexible and responsible when dealing with technological innovations.

This is one provision which you will hear a great deal about, and I wanted to clarify what we are trying to do. There may be some confusion among the lawyers as to whether the authority is now vested with the Department. I see no reason why we ought not to clarify it and make it abundantly clear, otherwise I think that the

Department may be faced with a lawsuit at some point to force them to pay for medicare coverage across-the-board, if they are going to pay for it at all.

I think that this discretion is reasonable, and I think we ought to spell it out in a way that gives them that full authority.

The other major provision that affects this committee authorizes medicare payments for immunosuppressive drugs used in connection with organ transplants that are reimbursed under medicare. My colleague, Congressman Walgren, was the principal sponsor of this provision and he is here to speak in favor of it. I would simply like to add a few words in support of it myself.

These drugs are essential if an organ transplant is to be successful. However, medicare cannot currently pay for them because of the general statutory prohibition on the payment of outpatient drugs that can be self-administered. But, by not paying for these drugs, the medicare program is impeding the form of treatment which is most appropriate from the standpoint of both the beneficiary and the medicare trust fund. Adopting this provision would constitute both good medicine and good economics.

Before I leave that point, I think it is important to realize that if cyclosporine, for example, which appears to be the most successful drug to aid in transplant surgery, is not taken after the surgery, then the surgery, even though it had been successful, may fail. In the case of a kidney transplant, the patient will be back on dialysis. The government will be paying for the continued dialysis of that patient.

One might say, "If a person is going to go through the surgery, wouldn't they pay for the drug anyway?" Perhaps so, but if they run out of money or cannot afford it, then we are putting that person back on full government payment for dialysis.

There is another point to realize as well. There are some patients, when they are told that they could have a kidney transplant, but after that surgery they are going to have to come up with out-of-pocket expenses for this drug for as long as they are alive, they will say, "I won't undergo the surgery. I will continue on dialysis for the rest of my life."

That is a decision that would be forced by economics. It seems to me not to make any sense when we realize that transplant surgery and even the costs of that drug thereafter would be far less than the cost of dialysis for that patient.

Those are the two major issues on medicare.

In the period since our committee acted on this bill there have been a number of individuals who have contacted us with questions concerning minor or technical interpretations of the legislation. While many of these issues were not raised during the committee hearings, a Commerce Committee amendment will be offered on the House floor to respond to those concerns within our jurisdiction.

H.R. 4080 is the product of extensive work by members of the Energy and Commerce Committee and leaders in the field of organ transplantation. Our hearings demonstrated that the current system for obtaining organs for transplantation is overwhelmed and inefficient.

The legislation has broad support within the health, medical and scientific communities. It has the endorsement of the American Society of Transplant Surgeons, North American Transplant Coordinators Organization, Association of Independent Organ procurement Agencies, South-Eastern Organ Procurement Foundation, American Heart Association, and the American Nurses Association.

I urge the subcommittee to act swiftly and report the legislation favorably to the House. The need is great. After my colleagues have completed their comments, I would be pleased to answer any questions that the committee may have.

Chairman JACOBS. Thank you very much, Mr. Waxman.

Our friend and colleague, Mr. Madigan.

**STATEMENT OF HON. EDWARD R. MADIGAN, A REPRESENTATIVE
IN CONGRESS FROM THE STATE OF ILLINOIS**

Mr. MADIGAN. Thank you, Mr. Chairman and members of the subcommittee.

I am pleased to join my friends from the Commerce Health Subcommittee to testify in support of H.R. 4080, the National Organ Transplant Act. I believe this legislation takes the necessary first steps to better coordinate and improve our Nation's organ procurement activities and organ transplantation.

The Subcommittee on Health and the Environment held four hearings on this issue and received testimony from experts in the field of transplant surgery and organ procurement. These witnesses brought to the subcommittee's attention the vastly improved effectiveness of transplant surgery over the past 5 years. Yet as technology has rapidly improved the effectiveness of transplantation, organ procurement and distribution activities have been limited.

Mr. Chairman, of the over 20,000 brain deaths in the Nation each year, less than 15 percent of these patients' organs are actually donated. Because of a lack of knowledge on the part of the general public, difficulties in coordinating organ procurements, and problems with financing operations and drug therapy, an often inefficient transplant network results.

This bill, as reported by the Energy and Commerce Committee, addresses the need for a framework to coordinate organ procurement activities and offers assistance to those organizations which serve those in need of transplants. H.R. 4080 provides grants to strengthen and expand local procurement organizations across the country.

The bill will also help to support a national organ computer system which will maintain a national registry of individuals who need organs, and will operate a national computer on a 24-hour telephone system to help match donated organs with potential recipients.

In addition, the bill allows the Secretary to designate centers for transplant surgery, so that under certain circumstances transplants would be eligible for medicare and medicaid coverage. At the Secretary's discretion, coverage decisions could be made on an individual basis, only if justified by medical and scientific evidence and expertise.

In addition, as has been mentioned by Mr. Gore and Mr. Waxman, H.R. 4080 provides for medicare coverage of immunosuppressive drugs for 3 years following a medicare-covered transplant surgery. Although these drugs are costly, they are essential to the success of transplants in reducing, and often eliminating, the need for repeat hospitalizations and graft rejection.

I might say, parenthetically, Mr. Chairman, that even the most conservative member of our subcommittee and our committee felt that if we were going to go into this, we ought to go all the way and provide for drug therapy or else there would be many people who we would simply be deceiving by saying to them, "We will make this operation reimbursable, but this \$8,000 first year cost for drug therapy and the \$5,000 subsequent cost for the next 2 years will be your responsibility to discharge," something that most people simply could not afford.

Finally, the National Organ Transplant Act outlaws the buying of human organs.

Mr. Chairman and members of the subcommittee, I want to reiterate my support for H.R. 4080. I believe the National Organ Transplant Act will strengthen the relationship between the Federal Government and the private sector health organizations and will leave the operation of the organ transplant system in the hands of the procurement and transplant centers which already exist.

I thank you for the opportunity to join my colleagues in testifying this morning on this very important issue.

[The prepared statement follows:]

STATEMENT OF HON. EDWARD R. MADIGAN, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF ILLINOIS

Mr. Chairman and members of the Subcommittee, I am pleased to join my colleagues from the Energy and Commerce Health Subcommittee to testify in support of H.R. 4080, the National Organ Transplant Act. I believe this legislation takes the necessary first steps to better coordinate and improve our Nation's Organ Procurement Activities and organ transplantation.

The Subcommittee on Health and the Environment held four hearings on this issue and received testimony from experts in the field of transplant surgery and organ procurement. These witnesses brought to the Subcommittee's attention the vastly improved effectiveness of transplant surgery over the past five years. This is largely due to the development of the immunosuppressive drug Cyclosporin, which has shown one-year organ survival rates of as high as 90 percent for human kidneys.

Yet as technology has rapidly improved the effectiveness of transplantation, organ procurement and distribution activities have been limited. Of the over 20,000 brain deaths in the Nation each year, less than 15 percent of these patients' organs are actually donated. Because of a lack of knowledge on the part of the general public, difficulties in coordinating organ procurements, and problems with financing operations and drug therapy, an often inefficient transplant network results.

H.R. 4080, as reported by the Energy and Commerce Committee addresses the need for a framework to coordinate organ procurement activities and offers assistance to those organizations which serve those in need of transplants. H.R. 4080 provides grants to strengthen and expand local procurement organizations across the country. These organizations do the difficult work of finding potential donors for those in need of organ transplants. Both hospital-based organ procurement programs and independent organizations will be eligible for these funds.

The legislation will also help to support a national organ computer system, which will maintain a national registry of individuals who need organs and will operate a national computer and a 24-hour telephone system to help match donated organs with potential recipients.

In addition, the act allows the Secretary to designate centers for transplant surgery, so that under certain circumstances transplants would be eligible for medicare

and medicaid coverage. At the Secretary's discretion coverage decisions could be made on an individual basis, only if justified by medical and scientific evidence and expertise. In addition, H.R. 4080 provides for medicare coverage of immunosuppressive drugs for three years following a medicare covered transplant surgery. Although these drugs are costly, they are essential to the success of organ transplants in reducing, and often eliminating, need for repeat hospitalizations and graft rejection.

Finally, the national organ transplant act outlaws the buying of human organs. It is feared that, in addition to the moral and ethical questions involved in the buying of human organs, this practice could lead to the breakdown of the voluntary-donation system. As a supporter of this legislation, I wholeheartedly agree that the buying of human organs should be made illegal.

The national organ transplant act has received the endorsement of the four most important associations representing organ transplant and procurement organizations. These are:

The American Society of Transplant Surgeons; the Association of Independent Organ Procurement Agencies; the North American Transplant Coordinators Organization; and the Southeastern Organ Procurement Foundation.

In conclusion, I want to reiterate my support for H.R. 4080. I believe the National Organ Transplant Act will strengthen the relationship between the Federal Government and private sector health organizations, and will leave the operation of the organ transplant system in the hands of the procurement and transplant centers which already exist.

Thank you again for the opportunity to testify on this important issue.

Chairman JACOBS. Thank you, Ed.
Doug.

STATEMENT OF HON. DOUG WALGREN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Mr. WALGREN. Mr. Chairman, I appreciate the chance to come and underscore with my colleagues particularly the importance of the reimbursement for the immunosuppressive drugs that are connected with transplant procedures. As Mr. Madigan has said, it is only commonsense that if we are to make an investment of the size that we make in individuals by giving them access to transplant procedures, that we recognize that the medical care and the costs that we see as essential to that medical care do not stop with the operating room, but rather continue certainly for a certain period, as this bill provides, the drug suppressive therapy that is now so effective.

I think there is nothing that has moved our public more than the vision on television of these young children that have been literally given life by advances in transplant surgery and medicine.

It was President Kennedy who said that life is unfair, and in many ways this particular advance in medical science is one of the striking things in our time that we have seen to make it more fair.

We have seen in November the approval by the FDA of cyclosporine as a drug for this use. I understand the reclassification by our Federal Government of liver transplants from the experimental category to the accepted medical category is imminent.

The advance that cyclosporine has made is literally unimaginable. It has reduced transplant failure rates from somewhere in the 50-60 percent range to less than 10 percent. It means that transplants could be the best medical procedure for patients with the most devastating illnesses.

It is also true that transplanting an organ is a much greater help to the quality of life after the transplant than trying to go through the ups and downs of periodic dialysis or other kinds of chemical

adjustments. This is a procedure that will be the medical procedure of choice. As Mr. Gore said, we have a real obligation to keep government policies up to date as science advances.

It is true that it just doesn't make much sense to pay \$20,000 a year for dialysis out of government funds when we could be paying as little as \$4,000 to \$6,000 a year for the necessary drug therapy to protect the transplanted organ. I don't believe that government has any more important function, other than save the national defense, than to make lifesaving medical treatment available to all in our country, regardless of economic status. That is the fundamental human instinct that goes back to the Hippocratic Oath where we provide medically for people without regard to economics.

I would ask you to focus on the commonsense of providing drug therapy coverage in this instance, and I appreciate very much the opportunity to come before you to underscore that.

[The prepared statement follows:]

STATEMENT OF HON. DOUG WALGREN, A REPRESENTATIVE IN CONGRESS FROM THE
STATE OF PENNSYLVANIA

It is an honor to appear here today on this panel with my distinguished colleagues from the Energy and Commerce Committee's Health Subcommittee to discuss the need for H.R. 4080, the National Organ Transplant Act. We welcome the opportunity to work with you in addressing the health needs of our nation.

Medical advances in recent years have been stunning and have given many people hope for an improved and sustained life. The development and the November 14 FDA approval of the drug cyclosporine a particularly significant step in enhancing the effectiveness of surgery to transplant human organs. As medicine and science advance, we in Congress have a responsibility to see that our policies keep pace. We must adapt the nation's health care and health insurance system, including Medicare and Medicaid, to these new realities.

Our Health Subcommittee heard from several outstanding surgeons, including Dr. Thomas E. Starzl, Professor of Surgery at the University of Pittsburgh in my home area. He stressed to us that we would be "penny-wise and pound foolish" to by policy decision encourage transplants and at the same time erect economic barriers to the effective and life-sustaining drugs that are necessary to prevent rejection of the organ. They testified that cyclosporine reduces hospitalization, results in fewer hospitalizations, and importantly greatly improves the rehabilitation status of transplant recipients. Therefore, he urged, medically, we should encourage the use of effective immunosuppressive drugs. In the full committee mark-up, I successfully offered an amendment which now appears as part of Title II of H.R. 4080 to provide funding for immunosuppressive drugs used in connection with organ transplants. The major drug involved here is cyclosporine.

Not only does this seem sound to our committee medically, it should be sound fiscally. Assuming that people who do not have transplants or who have unsuccessful kidney transplants have to go on dialysis, the \$4- to \$5,000 cost of a drug per year is far cheaper than the \$20,000 per year cost of kidney dialysis. The Congressional Budget Office discussion of cost appears on page 27 of our committee report. In short, we believe that the coverage of these drugs (now prohibited by statute) is not only good medicine but good economics.

Again, I appreciate the opportunity to appear this morning and urge your approval of this total bill. The challenge to make quality health care available to all at reasonable costs is one of the biggest this Congress faces. In this area, the National Organ Transplant Act is a giant step toward removing economic, geographic, and informational inequities in our system—offering hope to many people who otherwise face the prospect of death or debilitation.

Chairman JACOBS. Mr. Moore.

Mr. GORE. Mr. Chairman, the gentleman from New Mexico, Joe Skeen, is the ranking member on my Science Subcommittee and he participated in all of the hearings. His participation was extremely

valuable in drafting the bill. He could not be here this morning, but he wanted his support registered.

I would like to note for the record that among the more than 90 cosponsors, I want to give special recognition to the gentleman from North Carolina, Jim Broyhill, who is the ranking member in the Commerce Committee, and has been extremely helpful in this effort.

Chairman JACOBS. Thank you, Mr. Gore.

Mr. Moore.

Mr. MOORE. Thank you, Mr. Chairman.

Al, on page 6 of your testimony, you make the statement that problems of not knowing where to send organs when they have been donated have resulted in the tragedy of many organs being wasted. Do you have a number, so that we can get some kind of feeling for that?

Mr. GORE. One example that is frequently used involved the University of Pittsburgh, which is one of the major liver transplantation centers operating today. There were 300 livers that could not be used and were disposed of principally because, in that case, the transplant teams were otherwise occupied when the liver became available, or they were exhausted. They can't operate 72 hours straight, they have to get some sleep. Also there was great difficulty in getting them to the right place in the proper time.

Mr. MOORE. I understand, from information that we have been looking at, that a liver has about a 4-hour lifespan. So there is great difficulty in getting the liver someplace else. If it was in Pittsburgh, for instance, you really couldn't get it very far away and use it.

Mr. GORE. Unless you have split-second timing. If you have a donor that is listed on a kidney system, kidneys have 24 to 48 hours, then they have to go into a completely different network to track down the recipient of the other organs. The existing system is focused on the kidney problem, and time is lost.

You are right, when you have only a short time, about 8 hours for a liver, to work with, if you lose one of those hours, the transportation time to another city may mean that the organ is unusable.

Mr. MOORE. What I was wondering about is the number. You have given us the number of 300 out of Pittsburgh. How many of those really could have been used somewhere else, if they could have gotten someplace else?

Mr. GORE. We don't know for certain, but a good number of them could have been used elsewhere, perhaps as many as one-third.

Dr. Starzl is the leading expert from Pittsburgh and he will be testifying later. He can speak further to that point.

Mr. MOORE. Let me say to all four members of the panel, we certainly appreciate your being here. You have very busy schedules. You obviously feel very strongly about this bill. It is a serious matter and one I am sure that our chairman and all the members of this committee will take seriously.

I certainly agree at the outset that we ought to be doing everything we can to encourage donors. I understand that that is one of our big problems, the fact that we don't have people readily understanding how to donate an organ, how to be approached to donate

an organ. It is one of our biggest problems that people are dying without the ability to ever receive an organ transplant because the organs aren't there.

Second, I also agree with the comment that Mr. Waxman made in his testimony that we ought to prohibit the sale of organs. I think that this is something that the bill does that we all agree with, and something that I certainly would be very strongly in support of.

I thank all four of you.

Chairman JACOBS. Mr. Duncan.

Mr. DUNCAN. Thank you, Mr. Chairman.

I want to thank our colleagues for their great contribution.

Mr. Chairman, I have a letter from a Dr. David Gerkin of Knoxville, a part of which says:

My great concern, however, is the effect that it will have on local eye banks throughout the country of which I am a strong member and on the Board of Directors of the Eye Bank Association of America.

Representative Gore has told us that he will remove corneas from the bill when it is introduced to the committee; however, the basic problem is that all our banks have a processing fee, not for tissue, but for the processing which helps the survival of the eye banks. Also of great importance is that the eye banks are supported by, in most cases, civic organizations, in particular the Lions Clubs throughout the United States. These Lions are very active in sight conservation, as well as procuring eye wills, soliciting for eye tissue and doing things, that without them, we would probably be a great failure, in terms of eye banking.

Can you tell me, Mr. Gore, is that being addressed?

Mr. GORE. That is absolutely being taken care of, and I am glad you brought it up for the record. We have been made aware of that problem by the Eye Bank Association of America, and we are changing the bill to change the definition of "valuable consideration," so that it does not include the reasonable costs associated with removal, processing, preservation, quality control procedures, storage, and transportation.

I have discussed this with the Eye Bank folks, and this takes care of that problem. We are also removing corneas from the bill's definition of "organ." As I said in my testimony, we are addressing the vital organ problem. The outstanding work done by the Eye Banks around this country is really a great thing, and we are not going to affect that at all. It is not our intent to affect that at all.

Mr. DUNCAN. Mr. Chairman, I ask unanimous consent that Dr. Gerkin's letter be made a part of the record.

Chairman JACOBS. Without objection.

[Letter from Dr. Gerkin follows:]

MONTGOMERY, GERKIN, AND ANGE, M.D.'s, P.C.,
Knoxville, Tenn., January 12, 1984.

Hon. JOHN DUNCAN,
U.S. Representative,

Rayburn House Office Building, Washington, D.C.

DEAR SIR: As Medical Director of the East Tennessee Eye Bank, I am writing you concerning a bill that is currently in the House Ways and Means Committee which is of some concern to me. The bill in the Senate is Senate Bill 2018. This is the bill introduced by Representative Gore concerning the task force and organ procurement and transplant registry for other purposes. I feel that this is a worthwhile bill and has certainly great merit in terms of avoiding the possibility of tissues being bought and sold and control of what appears in the future to be a tremendously enlarging business, both medically, as well as financially.

My great concern, however, is the effects that it will have on local eye banks throughout the country of which I am a strong member and on the Board of Directors of The Eye Bank Association of America.

Representative Gore has told us that he will remove the corneas from the bill when it is introduced to the Committee; however, the basic problem is that all eye banks have a processing fee, not for tissue, but for the processing which helps the survival of the eye banks. Also of great importance is that the eye banks are supported by, in most cases, civic organizations, in particular the Lions Clubs throughout the United States. These Lions are very active in sight conservation, as well as procuring eye wills, soliciting for eye tissue and doing things that without them, we would probably be a great failure, in terms of eye banking.

The Kidney Foundation and other organ transplant organizations are quite different in that they have full time people sponsored by the government that solicit families at the time a patient becomes critically ill, working with one family 24 to 48 hours, in order for them to obtain one set of kidneys.

The number of corneas needed today are many many more times that of kidneys and the work that has been done by the Lions and by civic organizations throughout the country has allowed restoration of corneal blind people.

Because of its impact on the eye banks operating efficiently in this country, I feel that the bill is a bad bill.

I feel the bill introduced by Senator Hatch, Senate Bill 2048 which covers only a task force, an organ procurement and transplant registry and prohibition of organ purchase is probably a good bill and the one that we should push for.

I solicit your aid in this situation.

Sincerely,

DAVID G. GERKIN, M.D.

Mr. DUNCAN. Would one of you care to discuss the cost of H.R. 4080?

Mr. GORE. I would love to address that, because that is one of the strong points of the bill.

The Congressional Budget Office has done an extensive analysis of the legislation, and it has concluded that it is very close to zero costs, and there is a reason for that. We have now 70,000 Americans on kidney dialysis. Each one of those Americans is costing the ESRD program about \$25,000 to \$30,000 per year. A kidney transplant, which makes further dialysis unnecessary, is now costing in the range of \$40,000.

So if you take someone who is getting dialysis at an annual cost of \$25,000 to \$30,000, and give that person a kidney transplant at a cost of \$40,000, then you can see that in the first year you lose money, but by the third year you pick up money. There are 12,000 people each year on the waiting list for kidney transplants. Only about 5,000 of them are getting transplants each year.

There is some disagreement about this, but many medical experts believe that the number who should be on the waiting list, and who should be referred to transplants, ought to be as high as 20,000 per year. Even if you take a conservative estimate and double the 5,000, you are going to end up saving a good deal of money. That is not the principal purpose for passing the bill, but it is a negligible side effect.

Another provision which was inserted by the amendment of my colleague from Pennsylvania, including the cost of cyclosporine for 3 years after the operation, has also been found by the Congressional Budget Office to be a money saver because it cuts way down on rehospitalization and repeat procedures.

The net cost is very close to zero, in spite of the initial cost of these incentive grants which get the thing going.

Mr. DUNCAN. Thank you very much.

Thank you, Mr. Chairman.

Chairman JACOBS. Al, or anybody on the panel, in your testimony you made a distinction between tissue and organs.

Mr. GORE. Yes.

Chairman JACOBS. I have a feeling that the bill does not make that distinction, is that right?

Mr. GORE. The bill does seek to make that distinction, Mr. Chairman.

Chairman JACOBS. What about the definition section?

Mr. GORE. In the definition section, it does. It says that "the term 'organ' means the kidney, liver, heart, lung, pancreas," then there is a separation, "and other human organ or tissue included by the Secretary at his discretion."

We are going to specifically exclude corneas from that reference there, but even bone and skin would not be included unless and until the Secretary of HHS made a determination that that was in the best interest of this effort.

Chairman JACOBS. Why do you want to delegate that authority?

Mr. GORE. Let me try to say why. The principal focus of the bill is on vital organs. Many experts in the field believe that eventually the most effective and efficient way to accomplish this total effort is to make certain that a single donor donates not vital organs, but also the tissues.

In some states, Oregon, for example, they already do this very effectively. The Eye Bank people definitely want to be excluded from this effort, but they want to be notified when a donor is available, so that they can come in and retrieve the eyes. That would be a very efficient way to do it because you have these tight timeframes on vital organs—8 hours on the liver, and 24 hours on the kidneys—but then, after the heart has stopped beating and that effort has been completed, then the tissue people can come in and participate in the retrieval of the tissues.

Now the tissue banks, in their testimony before you, will ask for help. There is some disagreement in the tissue area between the Eye Bank and some of the other tissue people. We believe that the solution of the vital organ problem must proceed rapidly, and that we ought to leave open the consideration of tissues by the Secretary at a later time, but excluding corneas from his consideration.

Chairman JACOBS. I don't quite see how that ties in, "if it ain't broke, don't fix it," which I think you said earlier with respect to tissue. Did you have some other reference to tissue?

Mr. GORE. That was specifically a reference to the eye banks and corneas. It ain't broke, and doesn't need fixing. Some of the other tissue retrieval people, I believe that they do need help. Some believe that they ought to be separated in the definition section. We have had discussions on that, and we will keep an open mind about it.

It does seem to me from a public policy point of view that it does make sense to proceed rapidly on the vital organ part of the problem, and leave the door open to working out the problems of interfacing with the tissue banks later on. If the Secretary makes a formal finding through this, with the participation of all the parties, then they may be included later on.

Chairman JACOBS. Are you sure Congress shouldn't make that decision later on, that is my question?

Mr. GORE. Pardon me?

Chairman JACOBS. Are you sure that Congress shouldn't determine that policy according to the data that will be available later on? My only question was, why would you delegate that legislative authority, if it is a matter that is not entirely clear now?

Mr. GORE. I would urge you to question the tissue bank people on that very point because they are the ones who are asking for help on this. The experts in the field feel that, as we are beginning to establish the nationwide system, we ought to do it on a basis that includes all of it at the same time, excepting corneas, of course.

Chairman JACOBS. Mr. Rangel.

Mr. RANGEL. I don't have any questions.

Chairman JACOBS. Are there further questions?

[No response.]

Chairman JACOBS. We are grateful to all of you for having taken time from your busy schedules to come over.

The next panel consists of representatives of the U.S. Department of Health and Human Services, Dr. Edward N. Brandt, Assistant Secretary for Health; and Dr.Carolyn K. Davis, Administrator, Health Care Financing Administration.

Dr. Brandt, you come first; please proceed in your own manner.

STATEMENT OF EDWARD N. BRANDT, JR., M.D., ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. BRANDT. Thank you very much.

Mr. Chairman, I would like to go through summarizing my testimony, and request that it be put in the record in its entirety, if that is acceptable.

Chairman JACOBS. Without objection.

Dr. BRANDT. It is a pleasure to be before you, Mr. Chairman and members of the subcommittee, to discuss the activities of the U.S. Public Health Service in organ procurement and transplantation as they relate to H.R. 4080.

With few exceptions, no other issue confronting the Public Health Service at this time is as emotionally charged as this one. There is a natural tendency to associate organ transplantation with children who await suitable donors, and tragedies do occur when the child dies because no suitable donor organ is found. Congress, the administration—including the President of the United States—the media, and the Nation have all been touched by these deaths.

Daily, we confront the factors that affect the number of transplantations performed—the shortage of suitable donors, the lack of public awareness about organ donation, the lack of trained specialists and facilities, and the lack of knowledge on how to preserve organs. It is on these areas that I would like to focus my remarks.

Much of the work of the Public Health Service deals with the development of new knowledge in the biomedical sciences to improve our understanding of disease, its progression, its treatment, and its prevention. The National Institutes of Health has supported re-

search in organ transplantation for 20 years. It is now expanding its research on transplantation.

On January 6, 1984, five National Institutes of Health Institutes announced their desire to expand support on liver transplantation research in such issues as the pathogenesis of liver disease, ways to improve the technical aspects of transplantation, the immunology of rejection of livers, studies utilizing gene cloning and monoclonal antibodies, and the pharmacology of immunosuppressant drugs. We have copies of this announcement, which I will submit for the record.

Despite the NIH investment in research on methods for preserving organs, however, no new successful approaches have emerged. Clearly, better techniques for organ preservation will facilitate better utilization of donated organs.

Cyclosporine, a drug which is used along with adrenal glucocorticoids, to prevent graft rejection, was discovered in 1970 by Sandoz, the Swiss pharmaceutical company. Since 1979, the Food and Drug Administration has made it available for U.S. clinical trials, and in November 1983, it was given final approval.

The drug is not without problems, however. It is expensive and transplant recipients apparently have to take it for the rest of their lives. We still don't know what the long-term side effects may be. Whether children with liver transplants on cyclosporine will grow normally, what the long-term survival rates will be, what the long term risks are with respect to the development of cancer and repeated infections are all questions for the future.

We remain cautiously optimistic about its potential in kidney, liver, and heart transplants. At the same time, recent refinements in the surgical techniques and improved ancillary care have accounted for some of the increased survival rates that are now being observed.

At any rate, there appears no doubt that in the hands of the investigators carrying out the studies on cyclosporine, it is at least as satisfactory a treatment as the alternative regimens. Whether it will prove to have greater advantages over alternatives must be considered uncertain at this time.

New information on cyclosporine becomes available daily and exploration of its use in other transplants are ongoing or contemplated. Any summary of its current status is, therefore, outdated almost immediately.

NIH convened a consensus development conference in June 1983 on liver transplantation in which the skills, resources, and institutional support needed were discussed. Transplantation is probably not the ultimate answer to the treatment of end stage liver disease. Many questions remain unresolved.

In January 1984, the National Institute of Allergy and Infectious Diseases cosponsored a conference with the Upjohn Co., on the problems associated with multiple organ donation and procurement.

In 1982, 5,358 kidneys were transplanted, 15,000 corneas, at least 80 livers, 100 hearts, and 11 heart-lung combinations, the sharpest percent increase occurring with liver transplantation.

In the late 1970's, the Center for Disease Control developed an approach to organ procurement using public health principles in

order to demonstrate how to increase the numbers of organs procured. We have gone through some of that in the testimony, Mr. Chairman. That information has been shared with relevant organizations.

In my view, the CDC study clearly indicates that the present voluntary system of organ procurement can be managed well by the private sector. Beyond providing advice and assistance, interference by the Federal Government is unnecessary.

We must keep in mind, however, that even with the best system in place for procuring organs, not every person that needs a transplant is likely to obtain one. For example, despite the existence of 20,000 brain-dead persons annually, only an estimated 1,800 livers per year will be obtainable and suitable for transplantation.

Advances in transplantation technology over the last several years have pointed to the need for a more coordinated approach to organ procurement and donation. Voluntary organizations have traditionally taken responsibility for procuring organs for transplantation.

Early last year, the President of the United States asked the Surgeon General of the Public Health Service to assist with the problem of the critical shortage of suitable organs. Workshops that the Surgeon General convened in June and September culminated in the decision to establish the American Council on Transplantation. That decision was reached by persons representing 26 national organizations interested in transplantation. The first membership meeting of this organization was held on January 23 and 24, and it was attended by over 400 persons.

We have learned a great deal from our association with the organizations involved in organ procurement and transplantation. We recognize that there are gaps and that the current system is rather fragmented. However, the basic philosophies and the framework that guide their activities are sound, and we have already begun to see improvements taking place in the system.

Some of the major oil companies have pulled resources together to establish what is known as OIL Flights, a national emergency transportation network to fly transplant teams to retrieve organs and to fly potential recipients to transplant centers. A fleet of 43 corporate airplanes are available free of charge at this time.

Another private sector initiative called Life Page, sponsored by Telelocator, Inc., is providing beepers for people awaiting suitable donors. Several support groups are also being established to help families deal with the emotional trauma associated with losing a loved one, the financial burdens associated with transplant surgery and payment for cyclosporine, and mutual problems that are shared by transplant recipients.

The efforts of your colleagues in the House of Representatives, including the gentlemen who were here on the first panel, have played a major role in increasing the awareness of the private sector of the need to be able to meet the increasing demands for suitable organs.

The Office of Health Technology Assessment in the Public Health Service is responsible for conducting assessments of medicare coverage issues for HCFA. This office was asked to evaluate the safety and effectiveness of liver and pancreas transplantation.

The Public Health Service assessment of pancreas transplantation should be available sometime in the future.

We recently finished our assessment of the safety and effectiveness of the liver transplantation, and that report was forwarded to the Administrator of HCFA. I advised the Administrator to review the report carefully, and to proceed cautiously in making a final determination about coverage for liver transplantation. This country simply cannot afford to raise the public expectations beyond scientific reason. There are serious questions that remain regarding the selection of recipients for liver transplants.

Having said this, I would like to announce that at this time the administration supports Federal recognition of liver transplantation as a nonexperimental procedure for children with biliary atresia and other congenital abnormalities. Federal regulations implementing the above decision will be announced by way of the CHAMPUS program. Additional clinical trials should be and will be conducted for other conditions leading to end-stage liver disease.

My concluding remarks, Mr. Chairman, focus on H.R. 4080. In summary, we oppose the enactment of the bill because its objectives can be accomplished without legislation.

We have concerns about three specific elements of the bill. The first is the provision for the establishment of a new grants program to provide funds to establish or expand organ procurement organizations. The second is the establishment of a transplantation network that would maintain a registry of people who need organs to facilitate matching of donated organs with potential recipients.

I do not disagree that appropriate funding, as called for in the first provision, and the network, called for in the second provision, are important aspects of a national organ procurement program. I just do not believe that direct Government involvement in the procurement of organs will necessarily improve the system any further.

With regard to the proposed task force on organ transplantation, we feel that it would duplicate the efforts of a private sector organization currently undergoing its growing pains and becoming operational; namely, the American Council on Transplantation. We feel the establishment of the task force is not necessary.

The third provision would set up an identifiable entity in the Public Health Service to monitor the activities of the organ procurement agencies and networking activities, and to conduct a program of public education to inform the public of the need for organ donation.

I continue to believe that these are activities that traditionally have been and should remain in the private sector. We need to work together and not compete with one another. The critical question that this legislation raises is what is the appropriate role of the Federal Government in organ procurement and transplantation? I believe that we should proceed very carefully in this effort.

We are not opposed, of course, to make an annual report to the Congress on the scientific and clinical status of organ transplantation, but no new legislation would be required to carry out that provision.

Let me now address one element of title II of the bill. It permits the Secretary, after consultation with me, to establish medical cri-

teria about who can receive an organ transplant, who can perform the surgery, and where the surgery can be performed. These decisions are currently being established by transplant centers, by organized transplant teams, and by hospital administrators. The scope of physician practice and qualifications has traditionally been controlled by a combination of State licensure, hospital staff privileges, and certification by medical specialty societies.

I am opposed to Government intervention in determining the competence of physicians and other health professions. From the volume of my correspondence, I am not the only one that believes that the Federal Government should not be making these decisions.

In conclusion, I would like to comment this morning on the buying and selling of solid organs as addressed in title III of the bill. Secretary Heckler and I are opposed to the sale of human organs because we believe such activity is immoral and goes against the principles of medical ethics, particularly as recently determined by the AMA's appropriate body. However, we still recognize that we have to consider further whether Federal sanctions are needed or whether such activity should be dealt with at the State level. Some State legislatures, including Maryland and Virginia, have already introduced legislation to deal with this matter.

Mr. Chairman, this summary of the Public Health Service's activities should bring you up to date on our most recent work. We stand ready to provide further information on ways that we can reach our desired mutual goals. We believe that these goals can be obtained administratively without further legislation.

Now, Mr. Chairman, with your permission, Dr. Davis also has a statement.

[The prepared statement and attachments follow:]

STATEMENT OF EDWARD N. BRANDT, JR., M.D., ASSISTANT SECRETARY FOR HEALTH,
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman and members of the subcommittee, it is a pleasure to appear before you to discuss the activities of the Public Health Service (PHS) in organ procurement and transplantation as they relate to provisions in H.R. 4080. I am Dr. Edward N. Brandt, Jr., Assistant Secretary for Health, Department of Health and Human Services. With me is Dr. Carolyn Davis, Administrator of the Health Care Financing Administration (HCFA).

With few exceptions, no other issue confronting the Public Health Service (PHS) at this time is as emotionally charged as this one. Because there is a natural tendency to associate organ transplantation with children who await suitable donors, and because such tragedy occurs when the child dies before a suitable donor organ is found, the Congress, the Administration including the President, the media, and the Nation have all been touched by these deaths.

Daily we confront the factors that affect the number of transplants performed: the shortage of suitable donors, the lack of public awareness about organ donation, the lack of trained specialists and facilities, and the lack of knowledge on how to preserve organs. It is on these areas that I will focus my remarks this morning.

RESEARCH ACTIVITIES IN THE PHS

Much of the work of the PHS deals with the development of new knowledge in the biomedical sciences to improve our understanding of disease: its progression, its treatment, and its prevention. The National Institutes of Health (NIH) has supported research on organ transplantation for 20 years. In fiscal year 1983, NIH supported 297 projects, totalling \$40 million. The primary aims of this basic and clinical research are to develop procedures for the most effective selection of recipients prior to transplantation in order to minimize the risk of rejection, to identify the factors that trigger the rejection of transplants, and, to develop ways in which to treat rejection.

The NIH is also expanding its research on transplantation. On January 6, 1984, five NIH Institutes announced their desire to expand support on liver transplantation research in such issues as the pathogenesis of liver disease, ways to improve the technical aspects of liver transplantation, the immunology of liver rejection, studies utilizing gene cloning and monoclonal antibodies, and the pharmacology of immunosuppressant drugs.

Many of the medical and surgical techniques that have improved organ transplantation were products of research supported by NIH. Some transplant procedures are fairly well established in current clinical practice, such as cornea and kidney transplantation. Other procedures, such as heart, skin, bone, and, for some conditions, bone marrow transplantations, are gaining greater acceptance and clinical success. The patient indications for transplantation are still being refined, but some patients have enjoyed long-term survival for over 10 years with cornea, kidney, and heart transplants. Other procedures have only shorter term follow-up and long-term survival rates are not known. The NIH continues research on all transplantation approaches, particularly on procedures considered experimental, e.g., heart-lung, pancreas, and liver.

Despite NIH investment in research on methods for preserving organs, no new successful approaches have emerged. Although significant advances have been made in this area, more research needs to be conducted on ways to preserve organs *ex vivo*. At the present time, a donor heart can only be preserved up to 4 hours, a donor liver for up to 10 hours, and a kidney for 72 hours. A lung or heart-lung combination cannot be preserved at all. Better techniques for organ preservation will facilitate better utilization of available organs.

THE ROLE OF IMMUNOSUPPRESSIVE DRUGS IN TRANSPLANTATION

Cyclosporine, a drug used along with adrenal glucocorticoids to prevent graft rejection, was discovered in 1970 by the Swiss Pharmaceutical Company Sandoz. Since 1979, the Food and Drug Administration (FDA) has made it available for U.S. clinical trials, and in November 1983, it was given final FDA approval. The drug is not without problems—it is expensive and transplant recipients apparently have to take it for the rest of their lives. And, we still do not know what the long-term side effects may be. Whether children with liver transplants will grow normally, what the long-term survival rates will be, what the long-term risks are with respect to cancer and repeated infections are all questions for the future.

We remain cautiously optimistic about its potential in kidney, liver and heart transplants. Recent refinements in the surgical techniques and improved ancillary care have accounted for some of the increased survival rates that we are now observing. At any rate, there appears no doubt at all that in the hands of the investigators carrying out the studies on cyclosporine that it is at least as satisfactory a treatment as the alternative regimens. Whether it will prove to have great advantages over alternatives must be considered uncertain at this time.

New information on cyclosporine becomes available daily and explorations of its use in bone marrow transplants, pancreatic transplants and a variety of non-transplant situations are ongoing or contemplated. Any summary of its current status is, therefore, outdated almost immediately.

PHS ACTIVITIES IN LIVER TRANSPLANTATION

The NIH convened a Consensus Development Conference in June 1983 on liver transplantation in which the skills, resources and institutional support needed for liver transplantation were discussed. The consensus of the participants was the liver transplantation offers an alternative therapeutic approach which may prolong life in some patients suffering from severe liver disease that has progressed beyond the reach of currently available treatment and consequently carries a predictably poor prognosis.

Transplantation is probably not the ultimate answer to the treatment of end stage liver disease. Many questions remain unresolved. Substantial questions remain regarding selection of patients who may benefit from liver transplantation; the stage of their liver disease at which transplantation should be performed; survival and clinical condition of patients beyond the initial year after transplantation; and overall long-range benefits and risks of transplantation in the management of specific liver diseases.

As you are aware, the requirements for conducting a liver transplantation program are formidable. Very few hospitals and medical centers have the capability now to make a major commitment to support such a program. Experts at the consensus conference agreed that the transplantation surgeon must assemble and train

an extensive surgical and medical team and that commitment to the program requires operating rooms, recovery rooms, intensive care units, laboratory and enormous blood bank support at all times. These requirements offer the only assurance for high quality care in performing this very difficult operation.

Finally, the National Institute of Allergy and Infectious Diseases co-sponsored a conference with the Upjohn Company in January 1984 on the problems associated with multiple organ donation and procurement. Issues explored were: the means for obtaining more than one organ from a donor; guidelines that can be developed for intensive care units on how to maintain a brain dead donor, and the factors that interfere with identifying a donor early enough to ensure that the organs remain viable.

PHS ACTIVITIES RELATING TO ORGAN PROCUREMENT

Organ transplantation has been performed for over 20 years. In recent years, however, there has been a marked increase in the number of transplants performed. In 1982, 5,358 kidneys were transplanted, 15,000 corneas, 80 livers, 100 hearts, and 11 heart-lung combinations. The sharpest percent increase has occurred with liver transplantations. For example, since 1980, 370 liver transplants have been performed worldwide. This is compared to 170-200 in the preceding 17 years. With this increase in liver transplantation has come an acute awareness of the critical shortage of suitable donors. The absence of an available kidney, however, can be managed by renal dialysis while a transplant is awaited. The lack of a liver or heart for transplantation may mean death.

The Centers for Disease Control (CDC) in the late 1970's developed an approach to organ procurement using public health principles in order to demonstrate how to increase the numbers of organs procured.

This study was initiated to assess the number of kidneys potentially available for transplant purposes. Through this project, it was demonstrated that by applying a more systematic and timely approach to identifying potential donors, the number of organs actually procured could be increased. The results of this study have been disseminated in the professional literature. The CDC results also have applicability in identifying potential donors of many types of organs.

In my view, the CDC study indicates that the present voluntary system of organ procurement can be managed well by the private sector. Beyond providing advice and assistance, interference by the Federal Government is unnecessary.

We should keep in mind, however, that even with the best system in place for procuring organs, not every person that needs a transplant will obtain one. For example, despite the existence of 20,000 brain-dead persons annually, only an estimated 1,800 livers per year are obtainable for transplantation. This fall-off results from several factors, including the presence of disease affecting the organs, trauma to the organ as a result of an accident, physician reluctance to raise the issue of donorship with the family, unwillingness of next-of-kin to authorize the procedure, and varying State laws regarding organ donation and the legal definitions of death.

PRIVATE SECTOR INITIATIVES

Advances in transplantation technology over the last several years have pointed to the need for a more coordinated approach to organ procurement and donation. Voluntary organizations have traditionally taken responsibility for procuring organs for transplantation.

Early last year, the President asked the Surgeon General of the PHS to assist with the problem of the critical shortage of suitable organs. Workshops that he convened in June and September culminated in the decision to establish the American Council on Transplantation (ACT). The decision that such an organization was needed was reached by persons representing 26 national organizations interested in transplantation. Discussions with these groups have been grounded in two general assumptions:

It is wise to retain our present voluntary system of organ procurement.

The government should not try to dictate roles for an effort in which private-sector organizations have worked so earnestly and have achieved so much.

The PHS provided \$100,000 in core support for ACT through a cooperative agreement that was made in January. Private industry and professional organizations have provided monetary contributions as well as personal time, office space, legal, accounting and public relations services. The first membership meeting of this new organization was held on January 23-24 and was attended by over 400 persons. This organization will undoubtedly undergo the usual growing pains, but from my re-

ports, individuals and groups that attended that meeting walked away with a sense of hope for the future.

ACT has chosen four major goals to increase the availability of organs:

To motivate the public to donate organs and tissues for transplantation; to improve organ identification and referral to organ procurement programs by health professionals; to promote the effective distribution and use of multiple organs and tissues; and to ensure equitable access to organs and transplantation processes.

Long-range plans call for these goals to be achieved through initiation of a comprehensive program of public and professional education; improved communication and cooperation among organ procurement programs, health professionals and acute care hospitals; the establishment of standards for donor management, surgical recovery and preservation of donor organs; improved mechanisms for organ procurement and distribution; and studies to determine the current and future needs for organ and tissue transplantation.

We have learned a great deal from our association with the organizations involved in organ procurement and transplantation. We recognize that there are gaps and that the current system is rather fragmented. However, the basic philosophies and the framework that guide their activities are sound, and, we have already begun to see improvements taking place in the system. Some of the major oil companies have pulled resources together to establish "OIL Flights", a national emergency transportation network to fly transplant teams to retrieve organs and to fly potential recipients to transplant centers. A fleet of 43 corporate airplanes are available, free of charge, at this time. This network should cut down on the number of unused organs. OIL Flights complements several regional efforts that have also been established. For example, the Pittsburgh area has 15 planes that have been made available to transport the surgical team to recover organs, Memphis has 14 planes that have been made available, and I understand that Richmond has a similar effort underway.

Another private sector initiative "Life Page," sponsored by Telelocator, Inc., is providing "beepers" for people awaiting suitable donors. With a phone call, a transplant coordinator will be able to reach a waiting candidate anytime, anywhere during the important moments after a donor has been located.

Several support groups are also being established to help families deal with the emotional trauma associated with losing a loved one, the financial burdens associated with transplant and payment for cyclosporine, and mutual problems that are shared by transplant recipients. Organizations involved in organ procurement are updating and improving their communications networks to more effectively match donors with potential recipients. The efforts of your colleagues on this Subcommittee and others in the House have played a major role in increasing the awareness of the private sector of the need to be able to meet the increasing demands for suitable organs.

ASSESSMENT OF SAFETY AND EFFECTIVENESS

The Office of Health Technology Assessment (OHTA) within the National Center for Health Services Research is responsible for conducting assessments of Medicare coverage issues for HCFA. This office was asked to evaluate the safety and effectiveness of liver and pancreas transplantation. The PHS assessment of pancreas transplantation should be available sometime in the future.

The PHS made a determination in 1980 that liver transplantation was considered experimental. At the request of HCFA, OHTA began its reassessment of the procedure in April 1982. As is its usual practice, it published a notice in the Federal Register about its intent to evaluate this technology. At the same time, it contacted appropriate Federal agencies, medical specialty societies, and health insurance and manufacturing associations to solicit scientific and medical information regarding liver transplantation. With materials from these sources, information from the NIH Consensus Development conference on Liver Transplantation, and a staff review of the literature, OHTA developed its assessment and sent me a report regarding the safety and effectiveness of liver transplantation. This report has been forwarded to HCFA.

I advised the Administrator to review the report carefully and to proceed cautiously in making a final determination about coverage for liver transplantation. This country simply cannot afford to raise the public expectations beyond scientific reason. To me there are serious questions that remain regarding selection of recipients for liver transplants. For example, it was recommended at the NIH Consensus Conference that individuals who continue a pattern of substance abuse, and those with viral-induced liver disease and viremia and those with malignancy extending

beyond the margins of the liver should be excluded from candidacy. Furthermore, precise definitions are lacking as to which patients should undergo transplantation and at what state in the course of their illness it should be undertaken.

Having said this, I would like to announce that, at this time, the Administration supports Federal recognition of liver transplantation as a non-experimental procedure for children with biliary atresia and other rare congenital abnormalities. Federal regulations implementing the above decision will be announced via the CHAMPUS program. Additional clinical trials should be conducted for other conditions leading to end-stage liver disease.

Because definitive data on long-term survival rates just are not available on liver transplantation, generally, and especially on the long-term effects of cyclosporine, the PHS is urging that institutions performing liver transplants develop and maintain data available on a wide range of scientific, clinical and related issues. Data collection on long-term survival, morbidity and mortality, and quality of life would also be strengthened through this process. The PHS is currently exploring mechanisms for central coordination of data so collected.

LEGISLATION

My concluding remarks, Mr. Chairman, focus on H.R. 4080. In summary, we oppose the enactment of the bill, because its objectives can be accomplished without legislation. My overall concern is that the bill places too much emphasis on the mechanics of distributing solid organs. It falls short, however, of addressing ways in which the country can meet the increasing demands.

The PHS has concern about three specific elements of the bill. The first is the provision for the establishment of a new grants program to provide funds to establish or expand organ procurement organizations. The second is the establishment of a Transplantation Network that would maintain a registry of people who need organs to facilitate matching of donated organs with potential recipients.

I do not disagree that appropriate funding, as called for in the first provision, and the network, called for in the second provision, are important aspects of a national organ procurement program. Organ procurement organizations, whether they are independently run or part of a hospital, have established procedures for matching donated organs with potential recipients. Many of these organizations will be represented on the ACT. I have already described this effort earlier in my testimony. The existing system provides a solid base upon which we can build and improve. Although ACT is not the panacea for all the problems, I feel that we should wait until it has had a fair chance to deal with coordinating the activities of the various organizations. I just do not believe that direct government involvement in the procurement of organs will necessarily improve the system any further.

With regard to the proposed Task Force on Organ Transplantation, we feel that it would duplicate efforts of the ACT. Therefore, the establishment of the Task Force is unnecessary.

I would also like to emphasize that the private sector already has the capability of sharing organs within regions. Because of our inability to preserve organs for longer periods it may not be appropriate to develop a national registry of potential recipients, but rather maintain such listings on a region-by-region basis. I am also concerned that we might raise unrealistic expectations about the number of human organs that can technically be retrieved. There is a finite number of suitable organs, and, as I have already mentioned this morning, there are certain factors that limit the number that can reasonably be retrieved. This limitation will remain regardless of how we as a Nation elect to manage our organ procurement programs.

The third provision would set up an identifiable entity in the PHS to monitor the activities of the organ procurement agencies and networking activities, and to conduct a program of public education to inform the public of the need for organ donations. I continue to believe that these are activities that should remain in the private sector. We need to work together, not compete with one another. A critical question that this legislation raises is "What is the appropriate Federal role in organ procurement?" I believe that we must proceed very carefully so that all parties fully understand what is to be expected of us.

We are not opposed to making an annual report on the scientific and clinical status of organ transplantation, but no new legislation would be required to carry out this provision. We are also aware of the need to continue to evaluate the scientific and clinical status of organ transplantation, but here again, no new legislation would be required to accomplish this meaningful task.

I would now like to address one element of Title II of the bill. It permits the Secretary, after consultation with me, to establish medical criteria about who can re-

ceive an organ transplant, who can perform the surgery, and where the surgery can be performed. These decisions are currently being established by transplant centers, by the transplant team, and by hospital administrators. The scope of physician practice has traditionally and logically been controlled by a combination of State licensure, hospital staff privileges and certification by medical specialty societies. I am opposed to government intervention in determining the competence of physicians and other health professions. And, from the volume of my correspondence, I am not the only one that believes that the Federal Government should not be making these decisions.

In conclusion, I would like to comment this morning on the buying and selling of solid organs as addressed in Title III of the bill. Secretary Heckler and I are opposed to the sale of human organs because we believe such activity is immoral and goes against the principles of medical ethics. We are particularly concerned about those persons willing to sell their organs who may not fully understand the serious consequences of their action. However, we recognize we will have to consider further whether Federal sanctions are needed or whether such activities should be dealt with at the State and local levels. I understand, too, that some State legislatures, including Maryland and Virginia, have introduced legislation to deal with this issue.

Mr. Chairman, this summary of the PHS activities should bring you up to date on our most recent activities. We stand ready to provide further information on ways we can reach our desired mutual goals. I believe that these goals can be attained administratively, without legislation. I will be pleased to answer any questions you may have.

OHTA/NCHSR

A SUMMARY OF LIVER TRANSPLANT EXPERIENCE TO DATE

January 27, 1984

The attached tables outline the cumulative experience with liver transplants to date:

1. Attachment A outlines the world experience relating total numbers performed by center and year.
2. Attachment B presents survival data before 1979 (pre-cyclosporin) and from 1979 through August 1983 (post-cyclosporin).
3. Attachment C outlines age-dependent one year survival differences:
 - o in pre-cyclosporin era (before 1979)
 - o in cyclosporin era through May 1982
 - o in cyclosporin era May 1982 through August 1983
4. Attachment D tabulates total United States experience by center, numbers of transplants, and numbers of patients.
5. Attachment E outlines the 1983 experience in the United States.

Additional information on the doses of Cyclosporin-A used in the various centers will be submitted in a separate memorandum.

ATTACHMENT A

LIVER TRANSPLANTATION - WORLD EXPERIENCE

<u>CENTER</u>	<u>SURGEON</u>	<u>YEARS</u>	<u>TRANSPLANTS</u>	<u>PATIENTS</u>	<u>ADULTS</u>	<u>CHILDREN</u>
Denver	Starzl	1963-79	170	170	84	86
Pittsburgh	Starzl	1979-1/84	218	178	99	79
Cambridge	Caine	1968-82	138	137	131	6
Hannover	Pichlmayr		70			
Minnesota	Najarian	1974-83	45	45		
Holland	Krom	1979-82	20			
Memphis	Williams	1981-83	26	23	11	12
Birmingham	McMaster		4			
Boston	Moore		4	4		
	Russell	1983-84	10	9		
Davis	Ward	1982-83	8			
Royal Free	Hobbs		2			
Jackson	Raju	1983	1	1		
San Diego	Orloff	1983	7	7		
Total			723	574	325	183

Liver transplantation has also been performed in Paris, East Germany, Los Angeles, Montreal, New York, Oslo, Sao Paulo, Bonn, Belgium, and the Republic of China.

Results as of January 27, 1984

ATTACHMENT B

Survival Data Before 1979

Denver	N	1 yr Survival	Died 1 yr	Alive	Yrs Followup
(1963-76)	111	31 (28.8%)	18	13	6 1/2 - 13
(8/78-12/77)	30	15 (50%)	4	11	4 1/2 - 6 1/2
1977-1979	29	10 (34.5%)	1	9	2 1/2 - 5 1/2
	170	56 (35%)	23	23 (17.5%)	2.5-13
Cambridge					
(1968-74)	35	3 (8.6)	2	1 (2.8%)	
(1975-78)	39	11 (28.2)		11 (28.2)	
	74	14 (18.9)			

Survival Data Since 1979

Pittsburgh	N	1 Yr Survival	Died 1 yr	Alive	Yrs Followup
1980-5/1982	67	42 (62.6%)	6	36 (53.7%)	1-3yrs
Cambridge					
1979	9	4 (45%)			
1980	10	5 (50%)			
1981	14	4 (22%)			
1982	20	8 (40%)			
	53	22 (41.5%)			
Groningen					
1979-1982	22	12 (54.5)	0	12 (54.5)	1-3yrs
Hanover (1 yr survival figures unavailable)					
1972-1983	71	Totals		26 (36.6%)	1 mo-7 1/2 yrs

Results as of January 27, 1984

ATTACHMENT C

SURVIVAL DATA ACCORDING TO AGE IN THE PRE AND POST
CYCLOSPORIN ERA

<u>Age Group</u>	<u>Years Operated Pre-Cyclosporin)</u>	
	(1963-1976)	(1976-1977)
Pediatric	21/61 (34.4)	8/13 (61.5%)
Adults	10/50 (20%)	7/17 (41.2%)

1 year survival (4/1980-5/1982 cohort) (Clyclosporin Era)

Pediatric	19/26	70%
Adults	26/41	63.8%

May 1982-Aug 1983 (5-16 months followup)

Pediatric	16/28	(57%)
Adults	15/34	(44.1%)

Results as of January 27, 1984

ATTACHMENT D
TOTAL UNITED STATES EXPERIENCE
1963-1984 (Jan)

<u>CENTER</u>	<u>SURGEON</u>	<u>YEARS</u>	<u>TRANSPLANTS</u>	<u>PATIENTS</u>	<u>ADULTS</u>	<u>CHILDREN</u>
Denver	Starzl	1963-79	170	170	84	86
Pittsburgh	Starzl	1979-84	218	178	99	79
Minnesota	Najarian	1974-84	45	45		
Memphis	Williams	1981-84	26	23	11	12
Davis	Ward	1982-84	8	8		
Jackson	Raju	1983-84	1	1		
San Diego	Orloff	1983-84	7	7		
Boston	Moore		4	4		
Boston	Russell	1983-84	10	9		
Total			489	445		

Results as of January 27, 1984

ATTACHMENT E
RESULTS OF LIVER TRANSPLANTATION IN THE UNITED STATES

Outcome Experience
January-December 1983

<u>CENTER</u>	<u>TRANSPLANTS</u>	<u>PATIENTS</u>	<u>ALIVE</u>	<u>PERCENT</u>
Pittsburgh	105	76	53	69
Minnesota	15	15	9	60
Memphis	20	17	15	75
Davis	7	7	4	50
Jackson	1	1	0	0
San Diego	5	5	0	0
Boston	10	9	8	72
Total	163	130	89	

Results as of January 27, 1984

1982 Canadian Multicenter Randomized Trial
(209 recipients of cadaveric renal transplants)
(New England Journal of Medicine, October 1983)

	<u>1 yr. Graft Survival</u>	<u>1 yr. Patient Survival</u>
Cyclosporine Prednisone (103)	80.4%	96.6%
Azathioprine Prednisone (106) (Standard)	64% (p=0.003)	86.4%

Infectious Complications

	<u>Standard</u>	<u>Cyclosporine</u>
Septicemia	8	4
Abscesses	7	2
Fungal (Systemic)	2	1
Fungal (Local)	10	8
Cytomegalovirus	9	2
Other Virus	18	16
Urinary Tract	26	32
Wound	10	9
Pneumonia	6	6
Other	3	1

Noninfectious Complications

Table 4. Noninfectious Complications in the Treatment Groups

COMPLICATION	STANDARD TREATMENT	CYCLOSPORINE TREATMENT
No. of complications		
Urinary leak	4	6
Renal bleeding	8	5
Hydrocele or lymphocele	5	3
Renal artery thrombosis or stenosis	1	2
Systemic vascular complication	7	1
Hypertension	12	12
Cancer	0	2
Aseptic necrosis	3	1
Other musculo-skeletal complication	3	3
Severe leukopenia (<2000/ml)	12	1
Seizures	3	4
Major neurologic complication	0	3
Minor neurologic complication (tremor, paresthesias)	1	12
Psychiatric complication	4	3
Gastrointestinal hemorrhage	6	3
Other gastrointestinal complication	2	6
Steroid-induced diabetes	5	2
Clinical liver toxicity	4	1
Hirsutism	1	30
Gum hyperplasia	0	6
Cushingoid signs	19	17
Acne	18	13

No differences in incidence of rejections

U.S. Experience 1977-1980
Renal Transplants
(New England Journal of Medicine, June 1983)

<u>Patient Survival</u>	<u>Related Donor (#3491)</u>	<u>Unrelated Donor (#7595)</u>
1 yr.	95%	86%
3 yrs.	91%	78%
<u>Graft Retention</u>		
1 yr.	75%	56%
3 yrs.	67%	45%

University of Washington Study of 849 Patients
(New England Journal of Medicine, June 1983)

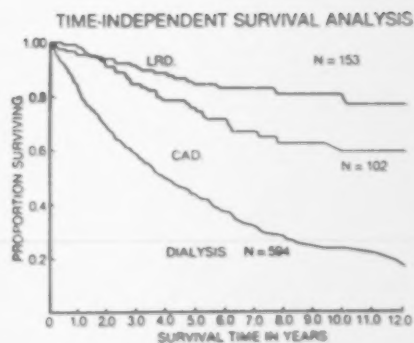


Figure 2. The Probability of Survival for 849 Patients with Primary Renal Disease Receiving Transplants from Living Related Donors (LRD) or Cadaveric Donors (CAD) or Being Treated with Dialysis Only.

Estimates were obtained by using the method of Kaplan and Meier.

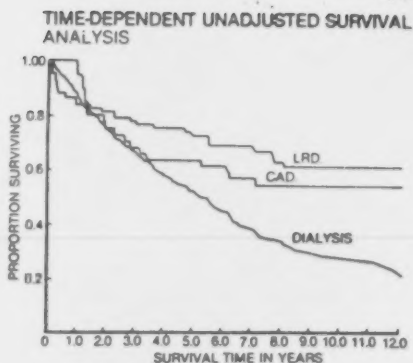


Figure 3. The Probability of Survival for 849 Patients with Primary Renal Disease, According to Transplant Classification.

Estimates were obtained by using the method of Kaplan and Meier, taking into account the time-dependent nature of the treatment status.

University of Cambridge
(New England Medical Journal, January 1984)

Cyclosporine

79 recipients of cadaveric
renal allografts

Azathioprine & Prednisolone

29 recipients of cadaveric
renal allografts

Graft Survival (not significantly different)

1 Yr	77%	62%
4 Yrs	70%	62%

Patient Survival (not significantly different)

1 Yr	88%	76%
4 Yrs	86%	76%

Cyclosporine did not reduce the incidence of rejections

ANNOUNCEMENT

LIVER TRANSPLANTATION RESEARCH

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND

DIGESTIVE AND KIDNEY DISEASES

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

NATIONAL CANCER INSTITUTE

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Application Receipt Dates: March 1, July 1, November 1

I. BACKGROUND INFORMATION

The above Institutes desire to expand their support of liver transplantation research. This announcement invites applications for individual research projects (R01 and R23) and supplements to existing Program Project grants (P01). In making this announcement, the intent is to encourage investigator-initiated research in the broad area of liver transplantation research. The research topics listed in Section II below are to provide examples but are not to be considered limiting.

The number of institutions now performing liver transplantation and the number of liver transplants being performed is increasing. A Consensus Conference on Liver Transplantation held at the National Institutes of Health (NIH) on June 20-23, 1983, concluded that "liver transplantation is a therapeutic modality for end-stage liver disease that deserves broader application". The availability of patients receiving transplants offers an important new resource for research into a variety of important questions concerning the pathogenesis of various liver diseases.*

*Digestive Diseases Advisory Board Report of 1983 - copies available from National Digestive Diseases Advisory Board, NIH
Liver Consensus Conference of June 20-23, 1983 - copies available from Office of Medical Applications of Research, NIH

These programs are described in the Catalog of Federal Domestic Assistance No. 13.848, Digestive Diseases and Nutrition, NIADDK; No. 13.855, Immunology, Allergic and Immunologic Diseases Program, NIAID; No. 13.399 Cancer Control NCI; No. 13.865 Center for Research for Mothers and Children, NICHD; and No. 13.859 Pharmacological Sciences Program NIGMS. Grants are awarded under the authority of Public Health Service Act, Section 301 (42 USC 241) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.

Various investigators currently involved with liver transplantation, having access to liver transplantation patients or material, as well as groups working on problems in general transplant immunology and pharmacology who could apply their expertise to problems of the liver, are encouraged to consider the areas listed, as well as many other unexplored areas of research that may improve the understanding of the pathogenesis of liver disease, the early identification and understanding of liver rejection, technical improvements in liver transplant procedure, pharmacology of immunosuppressant drugs and the use of monoclonal antibodies, liver regeneration and growth. The areas listed below are neither all inclusive nor directive but are meant to convey the wide array of disciplines and the excellent and diverse opportunities that exist. New applications, renewal applications with an expanded scope, and supplemental applications which incorporate liver research into ongoing programs such as transplant immunology of other organs, are all acceptable. The appropriate staff contact is indicated for each area or group of research topics.

II. RESEARCH GOALS AND SCOPE

A. Pathogenesis of Disease

- o Study of the recurrence or non-recurrence of disease in the donor liver may provide much information about the cause of the disease. The new liver will not carry the gene defect, and metabolic diseases which do recur must be due to extra-hepatic factors. Some conditions that can be examined are Wilson's disease, hemochromatosis, protoporphyria and storage diseases.
- o The ability of a liver transplant to reverse certain processes that result from end-stage liver disease can be studied, such as the bone disease of primary biliary cirrhosis, the neurological deficits in Wilson's disease, the chronic hepatic encephalopathy of cirrhosis.
- o In the hepatorenal syndrome, liver transplantation may correct the abnormality, implicating the liver in its pathogenesis. Substances such as vasoconstrictors may be looked for in the diseased liver.
- o In alpha-1-antitrypsin deficiency, both liver and lungs may be involved, yet liver transplantation may ameliorate the lung disorder and cure the liver problem. Is the new liver synthesizing and exporting alpha-1-antitrypsin to the lungs?
- o Can the study of liver transplant patients provide insights into metabolic diseases in which the liver performs a major functional role, such as the hyperlipoproteinemias?

B. Technical Aspects of Liver Transplantation

- o In some cases, host hepatectomy is extremely difficult and hazardous. For example, patients who have had previous surgery of the biliary tract, who have abnormal vessels or who have severe portal hypertension which usually results in massive operative blood loss. Can the procedure of auxiliary liver transplants be improved for these individuals? Currently, the success rate of the procedure is poor, but these procedures have not been tried with improved immunosuppressive therapy.

- o Crucial to successful auxiliary liver transplantation are studies into the importance, nature and mechanism of action of hepatrophic substances that help maintain liver growth and structure. The blood supply to auxiliary transplants would receive less of these substances than the blood supply of replacement transplants which receive virtually all of the blood drainage from the intestine.
- o Because of the limited number of donor organs, particularly for pediatric recipients, there has been some consideration of the use of a single lobe of liver for transplantation. From anatomical considerations, only the left lobe would appear suitable. Although this technique has been used in animal models, there have been no long-term human survivors. A far reaching clinical application of such research may be the use of living related donors.

C. Use of Resected Liver

- o Liver transplantation can provide investigators with a unique opportunity to study the liver in specific disease states. For example, the "autoimmune" nature of primary biliary cirrhosis and certain forms of chronic active hepatitis may be examined by eluting autoantibodies from the resected liver.
- o Immunologically active cells may be removed and tested in vitro for cytolytic and antibody producing potential.
- o The resected liver may serve to study the anatomy of the diseased liver; for example, the vascular supply of the biliary tree could be studied to define its relevance in biliary atresia.
- o The diseased liver may have accumulated abnormal metabolites which can be analyzed and may give a clue to the pathogenesis of the disease. This may be a unique opportunity for studying enzyme defects.
- o The cirrhotic liver might be harvested for mRNA for collagen to determine the molecular cause of the fibrous tissue deposition. Many other uses of the resected liver can be envisaged although any such use will require careful orchestration with the surgical team to obtain proper tissue. Various growth factors, enzymes, amines, etc., may be extracted from the resected liver.

Sarah C. Kalser, Ph.D.
Liver and Biliary Diseases Program
National Institute of Arthritis, Diabetes
and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7858

D. Immunology of Liver Rejection

- o Early rejections are usually reversible, but are much harder to detect in an organ such as the liver than they are in the heart. Therefore there is

a need to develop quantitative blood tests that are indicative of rejection. For instance, there may be different types of T-cells in the circulation under immunosuppression in the presence or absence of rejection.

- o What is the nature of the rejection reaction in transplanted livers? Given the liver's place in the reticuloendothelial system, there may be a much greater degree of delayed hypersensitivity type reaction with infiltration of macrophages rather than cytotoxic lymphocytes in the rejecting liver. Monoclonal antibodies could be used to characterize the inflammatory cells infiltrating the hepatic allograft.
- o What is the histopathologic picture of acute rejection; of chronic rejection?
- o What is the distribution of HLA antigens in human liver? Are they on the parenchymal cells, the bile ducts, Kupffer cells? If hepatocytes display few HLA antigenic receptors in comparison with bile duct cells, does this account for the patterns of injury that are observed in rejection?
- o Will matching of HLA tissue types of the donor and the recipient reduce rejection of donor organs and increase patient survival? Such matching is not now carried out prior to liver transplantation because of the limited availability of donor organs and because of time constraints between identification of donor organs and the need for their transplantation.

E. Monoclonal Antibody and Liver Transplant Survival

The advent of cell cloning and hybridoma technologies has made possible the systematic preparation of monoclonal antibodies specific for cell-surface antigens. These antibodies can be used to:

- o Monitor lymphocyte populations in candidate patients for liver transplants; monitor lymphocyte and non-lymphocyte populations that are introduced into the patient via the liver transplant.
- o Evaluate the use of monoclonal antibodies as therapeutic agents for preventing and/or abrogating rejection episodes.

Jane S. Schultz, Ph.D.
Genetics and Transplantation Biology Branch
Immunology, Allergic and Immunologic
Diseases Program
National Institute of Allergy
and Infectious Diseases
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5598

F. Immunology of Liver Rejection in Cancer Patients

In addition to basic studies of the immunology of liver rejection, studies aimed at facilitating engraftment of a transplanted liver in cancer patients are of interest. For example:

- o What is the role of passenger leukocytes present in the donor liver in the establishment of engraftment/rejection?
- o What is the relationship of the patient's general immune status and of any antitumor immunity in the establishment of engraftment/rejection?

G. Effect of Immunosuppression in the Cancer Patient

The role of the immune system in the control of metastatic tumor growth is an active area of basic research. For studies of liver transplantation:

- o It is important to evaluate the effect of immunosuppression on the exacerbation of any potential metastatic disease developing after transplantation.
- o The use of cyclosporin A appears to be beneficial for survival of the transplant patient. Studies of its effects on the various components of the immune system and on the subsequent course of disease in the cancer patient would be useful.

H. Immune Response to Hepatic Tumors

Primary hepatic malignancy confined to the liver but not amenable to resection may be an indication for transplantation. Results to date indicate strong likelihood of recurrence of the malignancy.

- o The availability of large quantities of involved liver may allow for studies of the profile (phenotype, immunologic reactivity) of immune cells infiltrating the various involved areas of the resected liver.
- o Does the nature of the immune cell infiltrate in the resected liver correlate with subsequent emergence of metastatic disease following transplantation?
- o What role, if any, does antitumor immunity play in effectiveness of liver transplantation as treatment for primary hepatic tumors?

Faye C. Austin, Ph.D.
Immunology Program
Division of Cancer Biology and Diagnosis
National Cancer Institute
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7815

I. Development, Regeneration and Nutrition

- o There is great potential for new knowledge on development of liver function by studying development of function in recipients of liver transplants.
- o Studies are needed on the regenerative properties of liver in infants and children. Experimental studies in animals directed toward the utilization of a single lobe of liver instead of the entire liver may allow the opportunity for studying the regenerative process. Should this experimental approach become feasible, it will be especially important to liver transplants in infants and children where the size of the transplant is a limiting factor.
- o The nutritional management of infants and children with disfunctional livers or who have received a liver transplant poses many problems. Assessment of nutritional status and matching of nutrients to the metabolic needs of these individuals are of great importance to clinical management.

Thorsten A. Fjellstedt, Ph.D.
Clinical Nutrition and Early Development Branch
National Institute Child Health
and Human Development
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5575

J. Pharmacology of Immunosuppressant Drugs

The liver is a major site of metabolism of many drugs and xenobiotics. Transformation by various enzyme systems within the liver, including the cytochrome P450 system, results in compounds which are more water soluble and thus more easily excreted. While many compounds are rendered inactive by this procedure, others are made more toxic. In patients undergoing immunosuppressant therapy following liver transplantation, it is important to know the metabolic status of the immunosuppressant drugs as well as any other drugs to which the patient may be exposed. Aspects of this study include, but are not limited to:

- o Effects of pre-existing disease state on the pharmacokinetics and metabolism of immunosuppressant drugs.
- o Effect of immunosuppressant drugs on the hepatic cytochrome P450 system.
- o Interaction of immunosuppressant drugs with other drugs, especially those affecting the cytochrome P450 system.

- o Genetic determinants of immunosuppressant drug metabolism.

Christine K. Carrico, Ph.D.
Pharmacological Sciences Program
National Institute of General Medical Sciences
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7181

In making this program announcement, it is not the intent of the above Institutes to make or imply any delimitation of investigator-initiated research in this field.

III. MECHANISM OF SUPPORT

The mechanism of support for this program will be the grant-in-aid. Research Project Grants (R01), New Investigator Research Grants (R23) and supplements to the preceding grants as well as to Program Project Grants (P01) will be accepted. The award of grants pursuant to this Program Announcement is contingent upon receipt of appropriated funds for this purpose. The specific amount to be funded will depend upon the cost of the research and the merit of the application. The earliest funding would be December 1984. All policies and requirements that normally govern the grant programs of the PHS apply. All applicants, both non-profit and for-profit institutions are eligible. This is not a one time invitation.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Procedure

Applications received in response to this announcement will be considered along with other non-solicited applications and will be assigned in accordance with the NIH Referral Guidelines. The initial review will be for scientific merit and will be carried out by an appropriate peer review group. The secondary review for relevance and responsiveness to the announcement will be made by the appropriate National Advisory Council or National Advisory Board.

B. Review Criteria

The factors considered to be important for review include a demonstrated knowledge of the applicable science, adequacy of facilities and commitment, availability of subject population, and in-depth knowledge of the state-of-the-art to which the announcement is directed. The application will be judged upon the overall scientific merit, adequacy of methodology, facilities and resources, commitment of time and cost effectiveness of the proposal.

V. METHOD OF APPLYING

Applications should be submitted on form PHS 398, the application for the traditional research grant. Application kits containing this form and the necessary instructions are available in most institutional business offices or from the Division

of Research Grants (DRG), NIH. The title "LIVER TRANSPLANTATION RESEARCH" should be typed in Section 2 of the first page of the application. The original and six copies of the application must be sent to the following:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

ANNUAL RECEIPT AND REVIEW SCHEDULE

<u>Receipt Dates</u>		<u>Initial Review Group</u>	<u>Council Meeting</u>	<u>Earliest Possible Start Date</u>
<u>Renewal, Supplements</u>	<u>New</u>			
Feb 1	Mar 1	June	Sept/Oct	December 1
June 1	July 1	October	Jan/Feb	April 1
Oct 1	Nov 1	February	May	July 1

Chairman JACOBS. I just wanted at this point to interpose a question. I can't help but be curious about it, Doctor; you testified that the Federal Government should not interfere with the judgment of medical doctors and other health authorities in the private sector. Does that mean that the Department would come down in opposition to the so-called Baby Doe legislation?

Dr. BRANDT. The Secretary has already, I think, made the views of the Department clear on that legislation.

Chairman JACOBS. I must have been out of town. What are the views?

Dr. BRANDT. There are letters that I think have been put forth. That issue has been handled by the civil rights mechanism of the Department. Since I have not read the letter, I am not clear.

Chairman JACOBS. You must have read about it in the paper, I was out of town. What is the position of the Department on the Baby Doe legislation?

Dr. BRANDT. The Department's position, I can send to you, sir, by letter.

Chairman JACOBS. Do you perceive a disparity between the position of the Department on the matter you just testified about and the so-called Baby Doe legislation?

Dr. BRANDT. The matter that we were just discussing was the issue of the Department deciding which surgeons can in fact do transplants, which nurses can assist.

Chairman JACOBS. Which in a sense is determining the safety of the procedure, isn't it?

Dr. BRANDT. However, I think that we have in place, sir, a wide range of mechanisms that are already accomplishing that and in fact, are working quite well.

Chairman JACOBS. With the indulgence of the committee, I don't usually do this, let me read one question, word for word, submitted by the staff.

You have testified in opposition to the medicare provisions giving the Secretary authority to limit the number of centers in which

organ transplants can be reimbursed under the medicare program. However, in the Public Health Service assessment of liver transplants, you recommend that liver transplants should be undertaken only in centers of excellence. Why don't you support the provisions in the bill giving you authority to designate centers of excellence?

Dr. BRANDT. I think the issue, sir, is that we certainly support that liver transplants, kidney transplants, cornea transplants, and any other kind of transplant should be done only in centers that are excellent and capable of performing those. The real issue is who determines that.

Chairman JACOBS. That is right.

Dr. BRANDT. In our view, since the Federal Government at the present time does not determine which hospitals and which surgeons can do a corneal transplant, or which hospital and which surgeons can do a kidney transplant, why should we now suddenly decide that it is time for the Federal Government to get into that act.

Chairman JACOBS. As I understand the question, it refers to the assertion that the transplant should be undertaken only in centers of excellence, giving such an exhortation to the private sector.

Dr. BRANDT. Yes, sir.

Chairman JACOBS. I assume that the Baby Doe legislation decision was made in some circles above the Department, is that correct?

Dr. BRANDT. I honestly do not know the decisionmaking process in that sense. As I said it was handled through the civil rights activities of the Department.

Chairman JACOBS. I was just struck by the apparent disparity in the administration's position since both involve, I suppose, life and death questions.

Dr. Davis, we are pleased again to welcome you to the subcommittee.

**STATEMENT OF CAROLYNE K. DAVIS, PH.D., ADMINISTRATOR,
HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF
HEALTH AND HUMAN SERVICES**

Dr. DAVIS. Thank you, Mr. Chairman.

I, too, am pleased to be here today to discuss transplantation in the medicare end stage renal disease program, and also comment on H.R. 4080, the National Organ Transplant Act. I would like to just briefly summarize the contents of my statement and submit the full statement for the record.

The overview of the end stage renal disease responsibilities is a part of the introductory section here, and then I move to some discussion of the activities of the kidney transplant program, primarily highlighting the medicare eligibility criteria for kidney transplants, pointing out the fact that coverage does end 36 months after the month of transplantation, unless the transplant fails and the individual begins a course of dialysis or receives another transplant.

I also point out some of the activities as they relate to medicare coverage and reimbursement for kidney transplantation, and some

of our activities in relationship to research and demonstration in the area of transplantation, primarily as it relates to the end stage renal disease program and a grant that we have given to Battelle Memorial Institute. That study is moving toward the final stage.

In terms of medicare coverage of the other organ transplants, I would simply like to point out that medicare does cover kidney and cornea transplants. We do cover bone marrow transplants also.

Under the medicaid program, we presently would match State funds for any organ transplants that they choose to cover, but it is a State decision as to their own coverage policy.

We have a national study financed by the Health Care Financing Administration underway to look at all aspects of coverage of heart transplantation, and that study includes an estimation of the potential need for heart transplants, the survival of heart transplant recipients, and the potential availability of the donors, cost of performing the transplants, the rehabilitation aspects, and quality of life of heart transplant recipients. Also the legal and ethical aspects of heart transplants.

That particular study and the evaluation of the study will be completed later this year. After the results have been reviewed, we will be making a decision regarding coverage of heart transplantation under the medicare program.

Dr. Brandt has already commented on the liver transplants, and I would simply like to point out that we have received the Public Health Service report entitled "Public Health Service Assessment of Liver Transplant," and the report does state,

Despite the appearance of safety, what is needed are studies that would generate an adequate data base upon which issues of safety and effectiveness can be brought into sharper focus in the context of risk versus benefits to the patient.

The Assistant Secretary for Health has expressed his own personal concerns that in many forms of liver disease, precise indications and the timing of liver transplantation remains uncertain or controversial. The long-term effects of cyclosporine are also not known at this time.

Consequently, he has recommended a scientifically cautious but reasonable course of action in the evaluation of liver transplantation, and we are studying that.

I would like to comment now on H.R. 4080, the National Organ Transplant Act, that has been reported by the House Energy and Commerce Committee.

Although the legislation is intended to strengthen the ability of the Nation's health care system to provide for organ transplants, we oppose the bill primarily because we believe that it is duplicative. There are substantial efforts that are currently underway in the private sector itself.

As you know, the Department of Health and Human Services has assisted in the formation of the American Council on Transplantation, which is composed of organizations, health professionals, and others in the private sector who are interested in all aspects of the transplantation system. I would like to add my support to that of others in the Department relative to the importance of supporting this private sector initiative.

I would like to also stress that from my own perspective as the HCFA Administrator, it is not feasible to consider funding the U.S. Transplantation Network from the Federal Hospital Insurance Trust Fund due to the precarious state of this fund at this time.

I would also like to point out that the United Network for Organ Sharing, which is operated by the Southeastern Organ Procurement Foundation, currently performs all of the key proposed functions of this network for kidneys, and it is linked with 144 out of 159 renal transplant centers.

Consequently, UNOS is an existing national network within the private sector which already fulfills the needs of national coordination, which we reimburse through medicare. We prefer this private sector activity to a federally regulated approach, particularly since medicare reimbursement provides the core support for these activities.

The provision which would establish grants for the initial operation or expansion of consolidated organ procurement organizations seems excessive in view of the fact that these organizations are already reimbursed for their reasonable cost of operation under medicare. Additional operating costs of the organizations, if they were to expand beyond kidneys, should be minimal, considering that there is already an existing capitalized organization with existing staff that could assume the augmented work scope with no need for startup costs.

HCFA has been conducting research on the operation of organ procurement agencies, and it will be receiving a report on this research in March of this year. The data to be reported will provide indicators as to what makes an effective organ procurement agency, and could be helpful to all of us in assisting us to devise a more efficient and effective approach to organ procurement.

Title II of H.R. 4080 would permit reimbursement under the medicaid and medicare programs for organ transplant procedures at designated centers. The Secretary, after consultation with the Assistant Secretary for Health, could determine that a specific health care technology or procedure furnished is reasonable and necessary only if the physician furnishing the technology or procedure, and the conditions under which the technology or procedure is furnished meet such medical criteria of general applicability which may be specified by the Secretary.

Determination of what is reasonable and necessary, conditions of participation for medical criteria of general applicability are issues that have traditionally been determined by HCFA. We are comfortable with the process of coverage determinations, working in cooperation with the Public Health Service, and we are very concerned about this new approach to selective approval of reimbursement in limited numbers or limited types of settings. These provisions of the bill would represent a major policy shift for medicare which we think is undesirable.

Section 202 would amend title XIX to require States to develop written policies regarding coverage under medicaid for organ transplants. In the absence of such policies, the State plan would be deemed to cover transplants in the same manner as medicare. It would also mandate that States pay for these services at the medicare rate.

Such unique treatment for organ transplantation seems inappropriate and goes counter to the trend of increased flexibility which have been accorded to the State medicaid programs. States have already had the responsibility for making coverage and reimbursement decisions for their own medicaid programs. This provision would take us in the opposite direction.

The intent of section 204 of H.R. 4080 is to provide for the payment of immunosuppressive drugs by medicare when the drugs are self-administered on an outpatient basis. Such coverage, again, would represent a radical departure from traditional medicare coverage. Medicare does not now cover self-administered outpatient drugs, and inclusion of such a benefit represents a significant precedent.

This section is intended to allow reimbursement of drugs approved by the FDA, furnished by recognized transplant centers on an outpatient basis, used in connection with a medicare covered transplant procedure. Payment would be permitted under the bill for up to 3 years after transplantation. Consistent with the medicare coverage of outpatient services, the standard deductible and coinsurance would apply.

The Food and Drug Administration fully approved cyclosporine on November 14, 1983. Cyclosporine will now be covered under medicare on an inpatient basis if it is reasonable and necessary according to accepted standards of medical practice and medical circumstances of the individual case.

No firm price for cyclosporine has been established by the manufacturer. However, approximately \$5,000 per patient is the estimate provided by manufacturer representatives.

Section 204 States that the Secretary would determine what payment amount is reasonable for the immunosuppressive drugs. This section further provides that payment would only be made on an assignment basis to the transplant center.

We note with great concern that in determining the amount of the medicare payment, the Secretary is directed to formulate a payment amount that is reasonable for the drug.

In determining the reasonable amount, the Secretary would have to consider, to the extent feasible, the amount which reasonably reflects the costs of producing the drug and furnishing it in an efficient manner. Since the economics of development and production of immunosuppressive drugs is new to HCFA, I believe it would be difficult for us, or for anyone else for that matter, to determine a reasonable payment to the satisfaction of any of the parties at interest—the medical centers, the patients, Sandoz, the physicians, or the Congress and this committee.

A reasonable charge methodology would also be problematic. Reasonable charges rely on the normal medical market in which services and supplies are customarily furnished by a large number of suppliers. In the case of cyclosporine, there is only one expected manufacturer which could impact on pricing and accessibility.

Requiring the transplant centers, which would distribute the immunosuppressive drugs, to accept assignment—in other words, accept a medicare payment level as payment in full—is questionable given the obvious difficulties in determining that payment level. Transplant centers could be financially at risk if the pay-

ment level found appropriate by the Secretary is lower than the manufacturer's charge.

I would like to point out, too, that 39 States have special entitlement programs which cover various aspects of treatment related to renal transplantation. Presently 35 States help pay for immunosuppressive drugs for renal transplant patients.

If this legislation were to be passed, individual States currently paying for immunosuppressive drugs might choose to curtail or terminate this drug coverage, thus shifting costs to the Federal Government which currently are borne by the States.

Finally, at a time when health care expenditures are of great concern, the addition of new benefits raises critical concern with regard to the continued economic stability of the medicare program. Our actuaries have estimated the cost of coverage of self-administered immunosuppressive drugs on an outpatient basis for renal transplants under the ESRD program at \$30 million in fiscal year 1984 rising to \$80 million in fiscal year 1989.

In summary, Mr. Chairman, we are opposed to the enactment of H.R. 4080 because of our concerns about extending medicare coverage at a time when the very solvency of the medicare trust fund is in question. We question the advisability of creating a bureaucratic system where the private sector is now doing an adequate job which will now be supplemented by the efforts of the ACT in coordinating the organ procurement efforts. We are concerned with the new approach to selecting and reimbursing transplant centers.

I would be pleased to answer any questions.

[Prepared statement follows:]

STATEMENT OF CAROLYNE K. DAVIS, PH.D., ADMINISTRATOR, HEALTH CARE FINANCING
ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Mr. Chairman, I am Dr. Carolyn K. Davis, Administrator of the Health Care Financing Administration (HCFA).

I am pleased to be here to discuss transplantation in the Medicare End-Stage Renal Disease (ESRD) program and H.R. 4080, The National Organ Transplant Act.

ESRD RESPONSIBILITIES

In 1972, Congress gave the Federal Government a unique role by providing medicare protection to persons with ESRD. Currently, Medicare protects approximately 93 percent of people receiving any ESRD services.

Medicare costs for ESRD patients were about \$2 billion in 1982. This was about four percent of total program expenditures and represents about 13 percent of part B expenditures. These expenditures were for 70,000 beneficiaries, or one quarter of one percent of Medicare beneficiaries, and they have grown much faster than were originally projected when the law was passed.

In July 1973, at the beginning of the Medicare ESRD program, there were approximately 15,000 ESRD patients, of whom 1,500 received transplants. In 1978, Public Law 95-292 was enacted to provide incentives for: (1) The use of lower cost, medically appropriate self-dialysis, particularly home dialysis, as an alternative to high-cost institutional dialysis, (2) elimination of program disincentives through use of transplantation, and (3) implementation of incentive reimbursement methods to assure more cost-effective delivery of services to patients dialyzing in institutions and at home.

To understand the treatment of ESRD, I would like to briefly describe the nature of ESRD. As you know, the function of human kidneys is to collect and dispose of body wastes formed in the blood during metabolism. ESRD is a permanent and irreversible breakdown of the capacity of the kidneys to carry out this disposal function.

ESRD requires artificial removal of these wastes through dialysis or replacement of the kidney through transplantation. Failure to provide treatment results in death.

There are two types of dialysis treatment: Hemodialysis and peritoneal dialysis. Transplantation is the other major treatment for ESRD and is more directly the subject of the hearing today. Transplantation is the surgical procedure which involves transplanting kidneys from living donors or cadavers into ESRD patients. In 1981, there were 4,883 transplants of which 1,458 or 30 percent were living-related donor kidneys and 3,425 or 70 percent were cadaveric kidneys. Of 5,358 transplant procedures performed in 1982, 1,677 or 31 percent involved living-related donors and 3,681 or 69 percent used cadaveric kidneys. During the first six months of 1983, there were 2,955 transplant procedures performed with the same percentages, 31 and 69, respectively, for living-related donors and cadavers. Transplants from living-related donors have yielded a lower rejection rate.

Between 1973 and 1982, there were approximately 38,650 transplants performed. As of the end of 1982, there were approximately 16,000 people with the functioning grafts. At the same time, there were 65,765 dialysis patients and about 6,700 of these patients were on a transplant waiting list. It is difficult to assess the actual percentage of this population who would be eligible for transplantation at any given point in time due to a variety of factors such as willingness of patients and co-morbid conditions. The number of transplants performed over the last few years has not, however, increased proportionately with increases in the overall ESRD population.

Research data indicate that a group of transplant patients will cost the medicare program less than a group of dialysis patients starting in the third year when considering aggregate costs across the three-year period for the respective groups.

MEDICARE ELIGIBILITY FOR TRANSPLANT RECIPIENTS

The Social Security Act provides Medicare entitlement for currently or fully insured individuals with End-Stage Renal Disease who require regular kidney dialysis or receive a kidney transplant. This coverage also applies to the individual's spouse or dependent child if one of them develops ESRD and initiates dialysis or receives a transplant.

The first day of coverage for Medicare varies depending on the mode of treatment. In general, an individual on dialysis receives benefits three months after the start of dialysis, or if an individual participates in self-care training during the first three months of dialysis, coverage begins the month a regular course of dialysis commences. An individual who receives a kidney transplant begins coverage with the month of the transplant or two months earlier if he or she is hospitalized in preparation for the transplant.

Coverage ends 36 months after the month of transplant unless the transplant fails and the individual begins a course of dialysis or receives another transplant or 12 months after maintenance dialysis is no longer necessary.

MEDICARE COVERAGE AND REIMBURSEMENT FOR KIDNEY TRANSPLANTATION

Both parts A and B (Hospital Insurance and Supplementary Medical Insurance) of Medicare help pay for kidney transplant surgery. Part A Hospital Insurance will cover the costs of inpatient hospital services for both the kidney recipient and the donor. These services may include a preevaluation, the kidney procurement, and the actual transplant operation. Part B medical insurance will pay for a surgeon's renal transplantation services on a comprehensive payment basis for services rendered during a 60-day period. The payment can vary depending on whether the renal surgeon performed other surgical procedures at the time of the transplantation or whether he/she provided supervision of the immunosuppressant therapy over a period of 60 days following surgery. This payment is a variation of the reasonable charge method used by the Medicare program to pay for all physicians' services. The maximum program amounts currently allowed by medicare carriers for renal transplantation therapy for 60 days, range from \$1,867 to \$3,052.

Payment to surgeons who perform cadaveric donor excisions is made at 100 percent of the reasonable cost under part A. A recent intermediary survey indicated that an average cost of approximately \$900 is paid by independent Organ Procurement Agencies (OPAs) for a surgeon's removal of cadaveric kidneys. All physicians' services rendered in connection with removal of the living donor's kidney are reimbursed using Medicare reasonable charges. Average payments are approximately \$1,100 for this service.

RESEARCH AND DEMONSTRATION PROJECTS IN TRANSPLANTATION

Research and demonstration is an important agency activity especially in ESRD and transplantation because of the escalating costs associated with the type of care needed by the ESRD patient. HCFA currently has a five-year plan for research and demonstration projects in the ESRD area, including transplantation.

A grant to Battelle Memorial Institute in 1981 examines for HCFA "The Impact of Alternative Types of Therapy on Patients with End-Stage Renal Disease." Among other things, the study focuses on several variables, including an examination of the quality of life, the quality of care, and the cost of care to patients undergoing different types of therapy for treatment of ESRD. Four treatment modalities are included in the study—facility dialysis, home hemodialysis, continuous ambulatory peritoneal dialysis, and renal transplantation,

Through our grant solicitation process, we are currently seeking proposals which would analyze factors affecting patient and graft survival, and proposals to develop and test systems that include incentives to promote availability of kidneys. Nine applications for study in these areas were received by the closing date of January 9 and are currently being reviewed for awards during the application cycle. We hope that future research on ESRD issues will provide the needed data to revise and reshape our policies affecting this severely ill population.

MEDICARE COVERAGE OF OTHER ORGAN TRANSPLANTS

The Medicare program's coverage of organ transplants is limited to kidney and cornea transplants. Medicare also covers bone marrow transplants. Under the Medicaid program, we presently match the states' funds for any organ transplant they choose to cover.

The law states that Medicare should pay only for those services which are reasonable and necessary. Therefore, Medicare does not pay for devices, procedures, or techniques that are considered to be investigational. When a coverage issue such as an organ transplant is brought to HCFA's attention—by, for example, one of our fiscal contractors or a regional office—the Office of Coverage Policy conducts a search of the medical literature and also reviews any other background material that has been submitted regarding the issue. If it appears from these reviews that the device or procedure may be in an investigational state of development, the issue is referred to the HCFA Physicians Panel for review. That Panel either resolves the question or refers it to the Public Health Service (PHS) on either an informal inquiry basis or with a request for a full assessment as to safety and efficacy. Informal requests usually involve an intensive review of the medical literature, discussions with other government components, and clarification of, and response to, specific questions raised by the panel.

In addition to the steps described above, a full assessment as to safety and efficacy involves the consultation with affected medical specialty groups and other professional organizations and the gathering of information as to the consensus within the medical community regarding the safety and efficacy of the service or procedure. When PHS has completed the information-gathering and evaluation process, it represents a formal report to HCFA with respect to the safety and efficacy of the device or procedure, and HCFA then decides whether the device or procedure should be covered by Medicare.

The question of Medicare coverage has arisen with respect to coverage of heart transplants, liver transplants, and pancreas transplants. I would like now to describe briefly our consideration of each of these types of transplants.

HEART TRANSPLANTS

A national study, financed by HCFA, is now underway of all aspects of coverage of heart transplantation under Medicare. This includes (1) the estimates of the potential need for heart transplants; (2) the survival of heart transplant recipients; (3) the potential availability of donor hearts; (4) the cost of performing heart transplants; (5) the rehabilitation and quality of life of heart transplant recipients; and (6) the legal and ethical aspects of heart transplantations.

The study and the evaluation of the study will be completed later this year. After these results are carefully reviewed, HCFA will make a decision regarding coverage of heart transplantation under Medicare.

LIVER TRANSPLANTS

At the end of 1980, PHS responded to a HCFA request for guidance on liver transplants. The PHS determination was that liver transplants were still investigational.

Since then, cyclosporine, an immunosuppressant drug, had been more widely used, and there were some suggestions that it has had a favorable effect on liver transplantation. Therefore, in April 1982, HCFA referred the questions of safety and efficacy of liver transplants to PHS for reassessment.

HCFA has received the PHS report entitled "PHS Assessment of Liver Transplantation, 1983," developed after the National Institute of Health Consensus Conference. This report stated that "despite the appearance of safety, what is needed are studies that would generate an adequate data base upon which issues of safety and effectiveness can be brought into sharper focus in the context of risk versus benefit to the patient * * *." The Assistant Secretary for Health expressed his personal concerns that in many forms of liver disease the precise indications and timing of liver transplantation remain uncertain or controversial and the long-term effects of cyclosporine are not known at this time. He counseled a cautious and scientifically reasonable course of action at this time in the evolution of liver transplantation as a method of treatment of liver disease. HCFA is presently studying this complex clinical material.

PANCREAS TRANSPLANTS

HCFA has also asked PHS for its assessment as to the safety and efficacy of pancreas transplants, especially with respect to ESRD beneficiaries who are diabetic and who have undergone kidney transplants.

H.R. 4080

The improvement in survival rates of various transplantation procedures has led to increased public attention on the problems of the need for organs to transplant and for funds to pay for these expensive transplant procedures.

H.R. 4080 the National Organ Transplant Act, has been reported by the House Energy and Commerce Committee, and is now pending before this Committee. Although H.R. 4080 is intended to strengthen the ability of the nation's health care system to provide organ transplants, we oppose the bill since it is duplicative of substantial efforts currently underway in the private sector.

The Department of Health and Human Services (DHHS) has assisted in the formation of the American Council on Transplantation (ACT), which is composed of organizations, health professionals, and others from the private sector interested in all aspects of transplantation systems. Dr. Brandt has described this organization to you in detail, but I would add my support to that of others in the Department on the support of their private sector efforts.

As you know, Title I of H.R. 4080, the National Organ Transplant bill, would amend the PHS Act to authorize the Secretary to make grants for the planning, establishment, and initial operation of organ procurement organizations, set up a transplantation network; operate a scientific registry; and establish a Task Force on Organ Transplantation. I would like to stress that from my perspective as HCFA Administrator, it is not feasible to consider funding a U.S. Transplantation network from the Federal Hospital Insurance Trust Fund due to the precarious state of this Fund at this time. I would also like to point out that the United Network for Organ Sharing (UNOS), operated by the South Eastern Organ Procurement Foundation, currently performs all of the key proposed functions of this network for kidneys and is linked with 144 of the 159 renal transplant centers. UNOS is an existing national network within the private sector which already fulfills the need for national coordination and which we reimburse through Medicare. In keeping with our general philosophy, we much prefer this private sector activity to a Federal regulatory approach, particularly since Medicare reimbursement provides core support for these activities. The provision which would establish grants for the initial operation or expansion of consolidated organ procurement organizations seems excessive in view of the fact that these organizations are already reimbursed for the reasonable costs of operation under Medicare. If this additional funding is for organs other than kidneys, these amounts should be reduced significantly. Additional operating costs of these organizations should be minimal, considering there will be an existing capitalized organization with existing staff that will be assuming an augmented work scope with no need for start-up costs.

HCFA has been conducting research on the operation of Organ Procurement Agencies and will be receiving a report on this research in March of this year. The data to be reported will provide indicators as to what makes an effective OPA and could be helpful to all of us in assisting us to devise a more efficient approach to organ procurement.

MEDICARE AND MEDICAID AMENDMENTS

Title II of this bill would permit the reimbursement, under the Medicare and Medicaid programs, for organ transplant procedures at designated centers. The Secretary, after consultation with the Assistant Secretary for Health, could determine that a specific health care technology or procedure furnished is reasonable and necessary only if the patient, the physician furnishing the technology or procedure, and the conditions under which the technology or procedure is furnished meet such medical criteria of general applicability which may be specified by the Secretary.

Determinations of what is reasonable and necessary and conditions of participation for medical criteria of general applicability are issues that have traditionally been determined by HCFA. We are comfortable with our process of coverage determinations, and are very concerned about this new approach to "selective" approval of reimbursement in limited numbers and/or types of settings. These provisions of the bill represent a major policy shift for Medicare which we think is undesirable.

Section 202 would amend title XIX to require states to develop written policies regarding coverage under the Medicaid State Plan for organ transplants. In the absence of such policies, the State plan would be deemed to cover transplants in the same manner as Medicare. It would also mandate that states pay for these services at the Medicare rate.

Such unique treatment for organ transplantation seems inappropriate, and goes counter to the trend of increased flexibility which has been accorded to state Medicaid programs. States have always had responsibility for making coverage and reimbursement decisions for Medicaid programs. This provision would take us in the opposite direction.

If States cover procedures, but not all centers meeting Medicare requirements, Federal Financial Participation (FFP) is denied. States could find themselves having to bear substantial out-of-state transportation and service costs in order to cover transplants at Medicare-approved centers if there were no such centers in their own state.

IMMUNOSUPPRESSIVE DRUGS

The intent of section 204 of H.R. 4080 is to provide for the payment of immunosuppressive drugs by Medicare when the drugs are self-administered on an outpatient basis. This section developed out of a concern that the high cost of immunosuppressive drug therapy discourages patients from seeking transplantation as an alternative to dialysis. Such coverage would represent a radical departure from traditional Medicare coverage. Medicare does not now cover self-administered outpatient drugs, and inclusion of such a benefit represents to us a significant precedent. This section is intended to allow reimbursement of drugs approved by the Food and Drug Administration (FDA), furnished by a recognized transplant center on an outpatient basis, and used in connection with a Medicare-covered transplant procedure. Payment would be permitted under the bill for up to three years after transplantation. Consistent with Medicare coverage of outpatient services, the standard deductible and coinsurance would apply.

The Food and Drug Administration fully approved cyclosporine on November 14, 1983. Cyclosporine will now be covered under Medicare on an inpatient basis if it is reasonable and necessary according to accepted standards of medical practice and medical circumstances of the individual case.

No firm price for cyclosporine has been established by the manufacturer; however, approximately \$5,000 per patient per year for a maintenance dosage is the estimate provided by manufacturer representatives. Cyclosporine, as with all other FDA-approved drugs, will be covered under part A of Medicare; however, under Medicare part B, drugs are covered only if they are furnished "incident to" a physician's professional service and cannot be self-administered.

Two dosage forms of cyclosporine are available—an injection and an oral liquid. As a general rule, the injection would be used during the postoperative period or at anytime a patient is unable to take drugs by mouth. After that time, the oral liquid would be used in long term care therapy due to ease of administration. Coverage of the injection under part B would be permitted if "incident to" the physician's service; however, coverage of the oral liquid under part B is presently precluded by the law because it is self-administered. Thus, Medicare would not help pay for cyclosporine which is self-administered on an outpatient basis, just as it does not help pay for other self-administered outpatient drugs taken by Medicare beneficiaries.

Cyclosporine has been credited in the last three years with decreasing complications after transplant surgery. According to some studies, the growing use of cyclo-

sporine as an immunosuppressant therapy in transplant recipients is expected to decrease inpatient stays for transplant surgery.

Section 204 also states that the Secretary would determine what payment amount is reasonable for the immunosuppressive drugs. This section further provides that payment would only be made on an assignment basis to a transplant center.

We note with great concern that in determining the amount of the Medicare payment, the Secretary is directed to formulate a payment amount that is reasonable for the drug.

In determining a reasonable amount, the Secretary would have to consider, to the extent feasible, the amount which reasonably reflects the costs of producing the drug and furnishing it in an efficient manner. Since the economics of development and production of immunosuppressive drugs is new, it would be difficult for us—or anyone else for that matter—to determine a reasonable payment to the satisfaction of any of the parties at interest—medical centers, patients, Sandoz, the physicians, or the Congress and this Committee.

A reasonable charge methodology would also be problematic. Reasonable charges rely on the normal medical market in which services and supplies are customarily furnished by a large number of suppliers. In the case of cyclosporine, however, there is only one expected manufacturer which may impact on price and accessibility.

Also to be noted here are the additional costs incurred in the administration of cyclosporine which should be accounted for, i.e., clinical laboratory testing for the analysis of the amount of cyclosporine and histocompatibility testing for immunomonitoring. The Medicare program would be obliged to cover such tests as well. These costs can be substantial.

Requiring the transplant centers which would distribute immunosuppressive drugs to accept assignment, i.e., accept the Medicare payment level as payment in full, is questionable given the obvious difficulties in determining that payment level. Transplant centers could be financially at risk if the payment level found appropriate by the Secretary is lower than the manufacturer's charge.

Thirty-nine States have special entitlement programs which cover various aspects of treatment related to renal transplantation. Presently 35 states help pay for immunosuppressive drugs for renal transplant patients. If this legislation were to be passed, individual states currently paying for immunosuppressive drugs might choose to curtail or terminate this drug coverage, thus shifting costs to the Federal Government which currently are borne by the states.

Finally, at a time when health care expenditures are of great concern, the addition of new benefits raises critical concern with regard to the continued economic stability of the Medicare program. Our actuaries have estimated the cost of coverage of self-administered immunosuppressive drugs on an outpatient basis for renal transplants under the ESRD program at \$30 million in Fiscal Year 1984 rising to \$80 million in Fiscal Year 1989.

CONCLUSION

There is much yet to be learned about renal transplantation and associated immunosuppressant therapies. Today, I have attempted to describe the current Medicare ESRD program and the Medicare coverage policy with respect to drugs, including immunosuppressants, as well as provide some comments on proposed legislation and to give you an indication of our strong reservations about many of the provisions of H.R. 4080, as reported by the Committee on Energy and Commerce.

In summary, we oppose the enactment of H.R. 4080 because of our concerns about extending Medicare coverage when the solvency of the Medicare program is in question; we question the advisability of creating a bureaucratic system where the private sector is doing an adequate job which will now be supplemented by the efforts of ACT in coordinating organ procurement efforts; and we are concerned with the new approach to selecting and reimbursing transplant centers.

I would be pleased to answer any questions you may have regarding these matters.

Chairman JACOBS. Mr. Moore.

Mr. MOORE. Thank you, Mr. Chairman.

Dr. Brandt, the bill calls for the paying of this drug, cyclosporine, for 3 years.

Dr. BRANDT. Yes, sir.

Mr. MOORE. We assume that a child 2 years old receives a liver transplant. We pay for the drugs for 3 years, and at age 5, we cut them off.

Dr. BRANDT. That is what the bill does.

Mr. MOORE. It does not seem realistic to me as a politician that that is going to happen. I am saying that we are probably going to amend the bill to cover the payment of the drug for I don't know how long. Do you agree with that assessment?

Dr. BRANDT. I agree with that assessment. I seriously doubt that after you have a child who has been on the drug for 3 years that this Congress, or any other Congress, in session is going to permit that to occur.

Mr. MOORE. It seems to me that it is the first time—I think Dr. Davis covered that point, but this will be the first time that medicare will cover a self-administered drug?

Dr. DAVIS. That is correct, sir.

Mr. MOORE. Does this present somewhat of an equity problem? Don't we have other people in society who have just as heavy a drug need for just as serious a life threatening situation?

Dr. DAVIS. Congressman Moore, that is my major concern, that it would be precedent setting, and I am certain that there are a number of other individuals who have heavy courses of drug therapy who could also stand in line waiting for coverage because it would be a question of equity.

Mr. MOORE. It seems to me that maybe we ought to cover all of that, but we ought to take a look at doing it for everybody and what the cost is going to be, rather than singling out one case or one particular situation in a bill like this.

Dr. DAVIS. I think the cost would be enormous.

Mr. MOORE. While we are on cost, Dr. Davis, do you have any disagreement with the cost estimates of CBO on the proposed legislation?

Dr. DAVIS. Yes, sir, we do have a difference of opinion between our actuaries and the CBO actuaries. If I could briefly highlight some of the particular differences:

The Congressional Budget Office assumed that only 50 percent of the beneficiaries who actually receive a renal transplant would use cyclosporine. Our actuaries assumed that everyone receiving a renal transplant would be using cyclosporine, because the physicians obviously believe it does represent a significant improvement, and because it is likely to improve the success rate. Furthermore, because there are other potential sources of payment for the cyclosporine therapy.

We know, for example, that the medicaid program, and other State programs, as I mentioned, help to cover the cost of the drugs and private insurance are available. For all of those reasons, our actuaries did make the assumption that everyone would already be using cyclosporine.

Second, CBO's assumption was that coverage of cyclosporine would increase the number of transplants by approximately 500 per year. So the numbers would increase from 5,400 in fiscal year 1984 to approximately 7,800 transplants in fiscal year 1988.

Our actuaries do not believe that just by extending coverage we would be able to change the number of renal transplants. They

assume an approximate level of 6,000 transplants annually. It is clear that that also is one of the major differences between the two groups.

In terms of the cost of immunosuppressive therapy, the Congressional Budget Office assumed that the cost of the immunosuppressive therapy would be \$5,600 a year for the first year, and then \$4,300 in the second and third years, with no inflation. Our actuaries estimated that the cost of self-administration would be \$8,000 in the first year, and \$4,000 in years two and three, and a 10 percent inflation rate after that.

In addition, the Congressional Budget Office did not account for the offsetting medicaid savings due to the substitution of medicare payment for the self-administered immunosuppressive drugs. Our actuaries estimate that about 23 percent of the end stage renal disease population is eligible for both medicare and medicaid, primarily through the medically needy program. Thus, they estimate the offsets.

I think that those are the major reasons for the difference.

Mr. MOORE. What is the bottom line?

Dr. DAVIS. The bottom line is that we believe, using the most prudent and conservative assumptions, that it will be costing us \$40 million for fiscal year 1984 moving to \$80 million in fiscal year 1989. Those admittedly are conservative estimates, but I think our experience with estimation, particularly as it deals with the end stage renal disease program, would indicate that it is prudent to be conservative, because clearly our initial estimates on the end stage renal disease program were significantly off target.

Mr. MOORE. Dr. Brandt, according to your testimony—I think you touched on this, but I want to go back and see if I understand it correct—the bill calls for your office to certify the physicians who are to be allowed to be able to do these organ transplants, to certify the institutions where they can be done, and to select the people who can have it done or the patients who can receive the transplant. Is that correct?

Dr. BRANDT. That is correct.

Mr. MOORE. I may be not understanding things right, but is this the first time that we have asked the Department of HHS to certify physicians and hospitals able to perform certain procedures or receive certain patients?

Dr. BRANDT. It is the first time that I am aware of, Congressman, and we have gone back and tried to look into this. Certainly with respect to the U.S. Public Health Service, we at the present have no role in determining what patients will receive a particular procedure, which physicians will be permitted to do it, and which hospitals will be permitted to do it. This will be brand new for us.

Mr. MOORE. That causes me some disturbance, but I am not too terribly sure that the Federal Government is all that bright or that able to do that sort of thing. It has a sort of a chilling effect in my mind.

If this is such a great idea, why shouldn't we do this for hip replacements, or for neurosurgery. Those are very major surgical procedures. Why shouldn't the Federal Government certify which doctors can do them, or which hospitals they can be performed in, and

which patients can receive them, especially where medicare is paying the bill?

Dr. BRANDT. I am sure that all of that has been suggested. My own preference, of course, is that the Federal Government not do any of it, and that we let the medical profession determine who is competent to perform these procedures.

Mr. MOORE. There have been some critics on the establishment of the American Council on Transplantation, some saying that it is nothing more than a Department attempt to delay things, and side-track efforts for legislation, perhaps such as this.

Can you tell me, Dr. Brandt, exactly what has been the Federal Government's involvement in the formation and operation of the Council?

Dr. BRANDT. Yes, sir. In March 1981, the Surgeon General first met with people who were concerned with the problem of liver transplantation in children. It seemed clear from those meetings, and then from subsequent television appeals and other activities, that there needed to be some kind of organized approach.

In June 1983, with planning occurring obviously long before that, the Surgeon General convened a meeting with 26 organizations for the purpose of exploring what could be done. It was the decision at that meeting that some sort of private sector organization needed to be formed in order to accomplish the goals of attempting to solve liver transplant problems.

The Surgeon General then convened a second conference in September for the purpose of determining what kind of organization, and it was at that meeting that the groundwork for what is now known as the American Council on Transplantation was laid, officers were selected by the group, and work was underway.

Since that time, the Public Health Service has provided \$100,000 to the group under a cooperative agreement arrangement. Second, we have worked with other representatives of the executive branch to obtain legal help for the group free of charge, to obtain space for the organization, and various other things that they have asked us to do to get them started.

Other than that, we have had no involvement. We certainly do not consider this in any way a Federal Government activity, nor do we consider it in any way to be controlled by the Federal Government. I think that if you talk to people who are involved in that organization, they will not tell you that they are in any way puppets of the administration or the Federal Government.

Mr. MOORE. Getting back to the point made a moment ago about this bill calling on your office to set up the criteria for the patient, the physician, and the institution, with respect to transplant operations. It appears to me that this may well have a chilling effect on innovation and additional development. In other words, nobody can do anything without clearing it with the Government first, because the Government would have to certify who can receive the operation, who can perform it, and where it can be performed.

Do you have this concern that this can well begin to chill or hold back innovation? What happens if Johns Hopkins Hospital, not one of the approved centers, but a very fine teaching facility, decides to do some experimentation, can they do it under this bill?

Dr. BRANDT. I think they would probably be able to do some experimentation. However, certainly under this bill, as I read it, it says that only if the person furnishing the technology and the conditions under which it is furnished meets such medical criteria of general applicability as the Secretary may specify. Then it goes on to determine that payment will be made only under those circumstances.

That certainly would clearly say that hospital X could do a certain procedure, and hospital Y could not, ultimately. One might argue that that would be a good thing, that there are only centers of excellence, as the NIH and the Public Health Service have repeatedly said. We would say that for any procedure, however.

I think that procedures ought to be done in settings of excellence. Therefore, I don't think that it is necessary to set this particular one up, and to get the Government now involved in these kinds of determinations that are done very well at the present time.

Mr. MOORE. It just seems to me that when the Federal Government begins to determine who can do what, you are excluding a group of people, those that don't have the Government certification. It just seems to me that we have not done that before and yet this country has experienced the greatest medical technological increases of any country in the world. I am just worried that under Government guidance or regulation, you are going to be stifling that kind of innovation.

Dr. BRANDT. Yes, I think that that is absolutely possible. Furthermore, we already have in existence a number of very fine renal transplantation programs going on. People are receiving transplants, 5,000, nearly 6,000, a year ago. People are surviving these procedures and doing very well.

Why should the Government now come in and determine under regulations who they are going to get to operate and what surgeons they can have, and whether or not they can continue in business. Why interfere with a system that is working? I will quote an earlier speaker, "if it isn't broke, why fix it?" I don't see that system as being broke.

Mr. MOORE. One of the real problems, I think, that this bill does try to address—I am not sure that the bill does it successfully, but it is a real problem that we are all concerned about—is increasing the number of donors across the country. I think we all agree that every potential donor is not donating, therefore, we have potential patients who are not able to receive the needed transplants.

Can you tell us what is happening now in the private sector, or what is going on out there across the country to increase the awareness of potential donors and to get them to donate. In your opinion, how would you stack that up versus what this bill is trying to do?

Dr. BRANDT. I think that clearly one has to get to the American people and make them aware of the possibility of donating and to encourage them to donate.

You have to recognize that there are certain religious organizations that have strictures, at least, on the donation of organs. Getting away from all of that, we have attempted to do this through

focusing publicity on the issue. Hearings like this will certainly highlight this for the general public.

In addition to that, you will hear later from various medical organizations and see what they are doing to alert their members to this need and to remember this possibility when, in fact, they have patients who are brain dead and can donate.

In addition, States have moved to adopt a more uniform definition of death in their own statutes, so that we get around the issue of when is somebody dead and when are they not by State law. I think that we are making some progress.

One of the primary functions of the American Council on Transplantation, as they have adopted and defined it, is providing both public and professional information and increasing their awareness. I hope that that program gets underway very soon.

Mr. MOORE. I have never been in that sort of situation, but it would seem to me that if you have a parent who is about to lose a child, or it is brain dead, or you have some member of the family that is brain dead, whatever, the person closest to those people, rather than some sort of organization or some sort of Government agency, would be in a position to advise on the possibility of donating and encouraging the patient to do that. Am I right or wrong in this instance?

Dr. BRANDT. I would think that in general that is certainly correct. That is one of the reasons why we feel that increasing professional awareness is very important. It has got to go somewhat beyond the physician, it seems to me, and go also to other personnel within the health care setting, so that they can provide the kind of support, and yet the opportunity for that person and that family to make the kind of the decision that may be difficult for them to face up to.

Mr. MOORE. The bill talks about the transplantation network, which sounds like a good idea. I don't see how anybody can object to the fact that you have a computer terminal somewhere that can tell you who has an organ and who has a patient, and try to match them up. Is it necessary, however, for the Federal Government to fund that, or to do that?

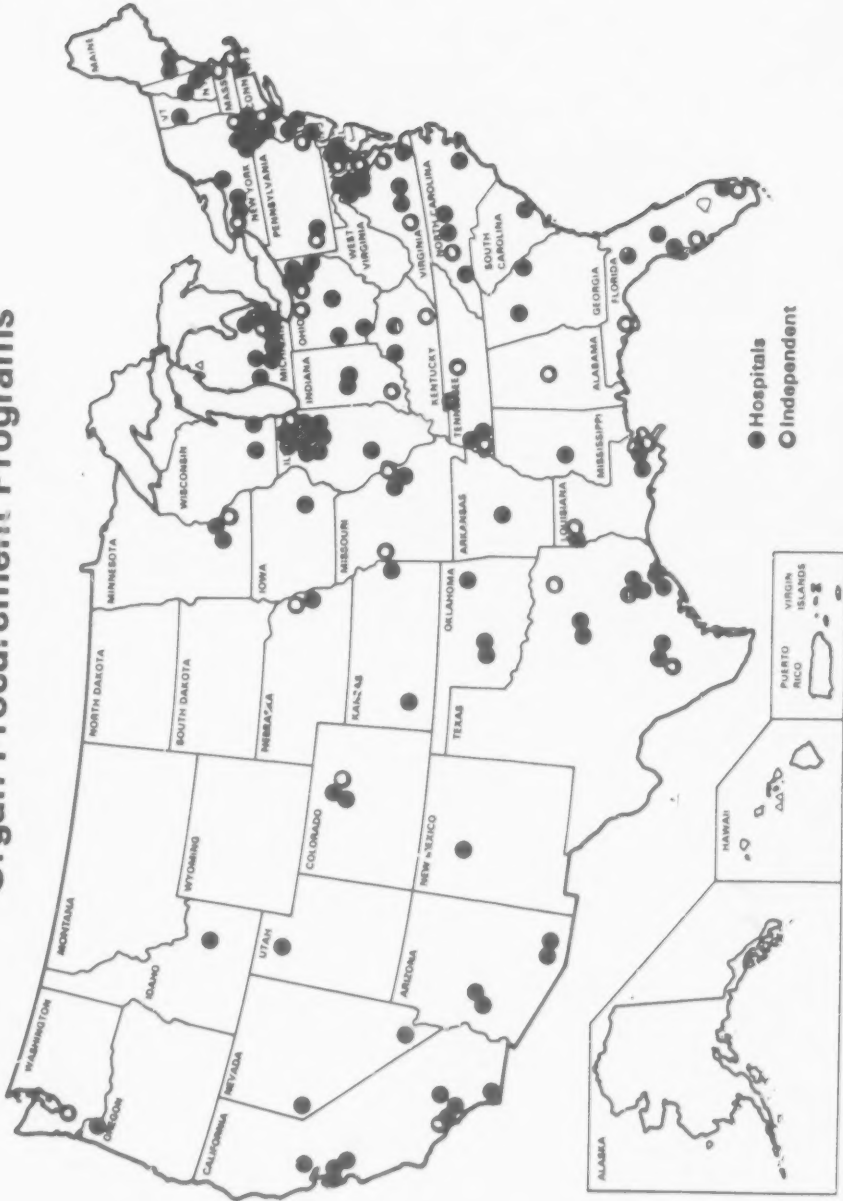
Dr. BRANDT. At the present time, under the renal system, which Dr. Davis can discuss in more detail, what is done is that procurement organizations are paid for their services. That is, they procure an organ, and payment is made to them. It is on that basis that they continue to operate.

We would certainly, as other organs get approved for coverage, anticipate that one of the costs that would be paid out of that would be the cost of procuring organs just as it is done now. Again, the renal system is operative, and perhaps Dr. Davis could elaborate on that.

Dr. DAVIS. I think, as was mentioned earlier, we have a number of organ procurement systems in place. In fact, I have a chart, if I could put it up, to show you the extensive coverage of organ procurement systems in the country.

[The chart follows:]

Organ Procurement Programs



4/19/83

Dr. DAVIS. There are 37 independent organ procurement agencies, and 80 hospital-based organ procurement programs. We pay for the cost of acquiring the organs and of transporting them. These are paid for under a reasonable cost basis.

Mr. MOORE. When you say, "We," who are you talking about?

Dr. DAVIS. The medicare program.

Roughly, the majority of the work that goes on in the organ procurement agencies, since they were funded initially for kidneys, is already being covered. Our estimation, in terms of the startup costs, is that it generally takes about \$125,000 for startup and capital costs. But those capital costs can be amortized over a 5-year period of time, and we, of course, would recognize those as part of the medicare payment under the reasonable cost system.

I think that it is important to note that the network system that is already tied in, the UNOS system, has 145 out of the 159 renal transplant programs, and most of the independent organ procurement agencies, do operate under this type of a network already. They have a computer patient matching file, and they have 24-hour telephone line and computer services, so that it does link a number of these facilities together already.

The fact that it has been more and more successful, I think, is indicated by the fact that the unused donor kidneys have dropped from 23 percent in 1981 to 15 percent unused kidneys in 1983.

Mr. MOORE. This is the kidney situation.

Dr. DAVIS. Yes.

Mr. MOORE. Is something like that in the works, or underway, or in operation now for liver transplants, or hearts, or pancreas, or whatever else that can be transplanted?

Dr. DAVIS. Not that we pay for. Many of these organ procurement agencies do use the same facilities. We simply don't recognize the cost of those other organs since medicare does not pay for transplantation of either hearts or livers.

Mr. MOORE. But is a network now in place for those?

Dr. DAVIS. The network is in place, and I am told that in many of the organ procurement agencies, the independent ones as well as the hospital programs, they do use the same technicians, the same services. Roughly about 90 percent of all of their time is spent harvesting kidneys because that has been the biggest area in the past. The other percentage of time they simply allocate to collection of the other organs, and we deduct that from the costs, since the medicare program does not recognize the cost of procuring those organs yet.

Mr. MOORE. What I am trying to get at is, what does the bill do differently from what is being done now in this area of networking and organ procurement?

Dr. DAVIS. I think that the bill simply offers funding for the creation of new organ procurement agencies, to stimulate further ones, as well as to network them. It also mandates that there is a selection in a geographic area in which the organ procurement agency is then implied to have general responsibilities for the particular area.

For example, in the D.C. area, we have five organ procurement agencies. It is my understanding that the bill would ask us to select

one of those as being the one that is responsible for coordination in this particular geographic area.

Mr. MOORE. You would select one for Federal funding, and eliminate the other four?

Dr. DAVIS. The bill is a little silent on the elimination of it, but it does clearly speak to the fact that one particular organ procurement agency should be responsible within the geographic area for networking.

Mr. MOORE. So a very aggressive OMB, in trying to save costs, could force you to potentially say, you only have to pay for one in the D.C. area.

Dr. DAVIS. I think that it would be inappropriate for me to conjecture what would be approved in the future.

Mr. MOORE. What we are saying is that instead of having five operating here you could wind up with one operating in the District of Columbia with Federal funding. That seems to be going in the opposite direction of where the bill would like to go. That is what you get into, I assume, when you have the Federal Government pick out who does what, and who qualifies for what.

Mr. RANGEL. The others would close, is that what you are saying?

Mr. MOORE. They wouldn't receive Federal funding.

Mr. RANGEL. So they would close.

Mr. MOORE. Not necessarily.

Mr. RANGEL. I was just trying to see how far you would go.

Mr. MOORE. It is just that medicare would not pay for them.

Mr. RANGEL. So they would go out of business.

Mr. MOORE. That is a good question. You would have to ask them that.

Mr. RANGEL. I thought that you were speculating that.

Mr. MOORE. When they lose Federal funding, it can do some damage to these organizations, I would assume.

Mr. RANGEL. They have never had it, so I don't see how they could lose it.

Mr. MOORE. They are getting it for certain organ transplants.

Dr. DAVIS. The organ procurement agencies do receive the cost now for kidney transplants.

Mr. MOORE. They are getting it.

Mr. Chairman, you have been very lenient with the time. I think that these are all the questions I have for the moment.

Chairman JACOBS. Mr. Rangel will inquire.

Mr. RANGEL. I assume from your testimony that you are satisfied that there is nothing more that the Federal Government can do in terms of networking and procurement of vital organs?

Dr. DAVIS. No, sir. I believe that there is more that we can do. In my testimony, I did mention the fact that we have had a study looking at the potential successes in the organ procurement systems that are currently in place for kidneys, and the results of that particular research effort will be in in March.

We do anticipate using the data and the results of that. We will learn what makes those activities most effective. We can then apply those particular solutions to the various agencies.

Mr. RANGEL. I got the opinion from your response to Mr. Moore's questions about what the private sector networking has for other

organs, that you really didn't know but that you assumed they had something similar to what they have for kidney transplants.

Dr. DAVIS. My comment was meant to indicate that since the medicare program only funds or pays for the kidneys, those transplants are the only ones that we track. I do know from the personal interaction with some of the organ procurement agencies that they do engage in the collection of other organs and the transport of them. But since the medicare program does not pay for those services, we don't have an accurate tracking system on those.

Mr. RANGEL. But we would not really know, as it relates to other organs, whether or not there is any networking at all by the private sector, would we?

You don't track it, so you don't know what is out there?

Dr. DAVIS. In relationship to tracking, do we know what is out there, I believe that there is a network that is already appropriately acting. We have spoken about the efforts of the American Council on Transplantation to coordinate the private sector effort.

Mr. RANGEL. I appreciate the emphasis that the administration places on the private sector, and know that it is your responsibility to track and be accountable for those Federal funds that are being reimbursed through medicare.

What we are saying here is that there is no need for the Federal Government to get involved, there is no sense in duplicating what the private sector can do. Yet, I think you are saying that we are not certain what we are doing in programs that are not reimbursed by the Federal Government.

Dr. BRANDT. I think, Mr. Rangel, that what we are actually saying is that this goes beyond other organs. This moves the Federal Government into the kidney system and in effect says, the Federal Government will regulate something that is currently happening and currently going on out there without Government regulation. That we don't like.

Mr. RANGEL. I am not talking about regulating. I am talking about establishing a network where people will have a better understanding of what is available in terms of donors and people who are in need outside of the area of kidney transplants where we are involved.

Dr. BRANDT. You have some very distinguished transplant surgeon panels coming up. One of them, Dr. Starzl has been——

Mr. RANGEL. All I want to know is, are you satisfied that in this area, that the Federal Government should leave it to the private sector and, if so, what evidence do you have that they are doing a good job? Are we satisfied that no lives have been lost because the Federal Government is not directly involved in this?

To put it another way, Dr. Davis, in her opening statement, discussed the ballooning cost of medicare as it relates to covering kidney patients. Yet, we are not talking about the cost of these programs. You are saying, I think, that the private sector is already doing the job, and there is no sense in the Federal Government getting involved.

So it is not a question of saving lives by putting in Federal dollars. It is a question of all that can be done is being done by the private sector, and no lives will be saved by the Federal Government getting involved.

Dr. BRANDT. I do not think that the Federal Government getting involved in this area is going to save any additional lives that the private sector is not already doing. Clearly there are activities that the Federal Government must do, and I have reported on many of those. We need to develop better systems for increasing the lifespan of organs that are available, and so forth.

Mr. RANGEL. This is really consistent with the administration's policy of trying to get the Federal Government out of businesses, and out of the affairs of people when the private sector can do a more effective job, without Federal interference. Is that correct?

Dr. BRANDT. That is correct.

Mr. RANGEL. In your statement about it being immoral and unethical to sell organs, and you oppose that concept, you then go into whether the Federal sanctions are needed. Is that still consistent with the administration's free market theory that we don't want to get involved and place a hassle on buyers and sellers of organs?

Dr. BRANDT. No, sir. I think if you read the statement, the issue is more of a legal issue as to whether or not this is something that ought to be regulated by the States or ought to be regulated by the Federal Government.

One can, for example, say that commerce in human organs is in fact the practice of medicine. The Federal Government does not regulate the practice of medicine, and should not regulate the practice of medicine. That is regulated by State governments.

The question is, should the Federal Government get into that, and that in my judgment is more of a legal issue, and not a policy issue. There is no question about the fact that we do not favor the buying and selling of organs, but the question is who should do the banning. We know that some States are already stepping into that breach, as I am happy to say.

Mr. RANGEL. What would be this administration's answer if the question of medicare for end stage renal disease patients was first brought to the administration? Do you think that would be a proper area for the Federal Government to be involved with?

Dr. DAVIS. I think that that is purely conjecture, sir, because in fact we are involved and we have been since 1972.

Mr. RANGEL. I am asking, if we were not involved, would you have encouraged us to get involved?

Dr. DAVIS. I couldn't comment on that because of the circumstances—I would not have a total picture of what the circumstances would be, since we have been involved since 1972.

Mr. RANGEL. You have the circumstances here, \$2 billion in 1982, expenditures for 70,000 beneficiaries, or one percent of medicare beneficiaries. They have grown much faster than originally projected when the law was passed. All of this is in your statement. My question is, knowing the facts as they are, would the administration have supported the Federal Government being involved in the end stage renal disease under medicare?

Dr. DAVIS. We don't make our coverage determinations on the basis of costs only. We make our determination on the basis—

Mr. RANGEL. That is really the basis of my question, and I am glad that you responded to it.

Dr. DAVIS. We make our coverage decisions on the basis of safety and effectiveness, and whether or not a procedure is medically necessary, and reasonable, and safe and effective.

Mr. RANGEL. Your upfront statement, Dr. Davis, certainly spends a lot of time on the cost of ESRD.

Dr. DAVIS. Yes, I thought it was important to highlight the fact that that is an important part of the entire area, but it is not in terms of our decisionmaking for coverage the central focus. That is why it is inappropriate for me at this point in time to make a comment on that particular question that you asked, Mr. Rangel.

Mr. RANGEL. This drug, cyclosporine, that the people are going to testify is a miracle drug, prolongs life, and is a great discovery. Why is there such a sharp difference of opinion with doctors that work for the Federal Government?

Dr. BRANDT. I think, sir, that it is not doctors who work for the Federal Government. A recent article in the New England Journal of Medicine by scientists involved in the renal transplantation program have raised the issue. It is not whether or not the drug is effective, clearly the drug is. The question is, is it any more effective than the standard immunosuppressive therapies that are available.

Bob Temple of the FDA is here with us, and he can summarize additional information. I think the real question is, to what extent is it more or less effective than other alternatives that are available.

Chairman JACOBS. We will have to suspend for just a moment. We will come back as quickly as we can.

Mr. RANGEL. It is clear that your decisions on this bill are not based on dollars and cents, it is just that the private sector is doing a good job, and the Federal Government should not interfere.

Dr. BRANDT. That is correct.

Mr. MOORE. Let me make one quick comment, if I may, and I will be through.

Chairman JACOBS. Go ahead.

Mr. MOORE. I want to correct the record, Mr. Chairman. My example a moment ago of what the bill calls for in regard to drug coverage was incorrect. It does not call for coverage for people other than medicare patients. But the situation would still be the same, if you had a patient age 65, and then cut off drug coverage after 3 years, we would have the same political pressure on us to continue payment.

Dr. BRANDT. All patients that get renal transplants are covered by the medicare program under the end stage renal disease program. So it doesn't make any difference how old they are, if they get a renal transplant, they would be covered under that provision.

Chairman JACOBS. I think the observation should be made for the record on this question of the prohibition against the sale of the organs, we might call it the shylock provision of the bill. I can't comprehend how the States are adequate to that task since the sales would be made in interstate commerce. Can you see how that can happen?

Dr. BRANDT. The organ has to be purchased some place.

Chairman JACOBS. You understand the concept of interstate commerce. It was discussed in the debates in the founding of our country. I fail to comprehend how the States could effectively regulate

or prohibit the sale of these organs since they are in interstate commerce.

Dr. BRANDT. A number of States have opted to do that.

Chairman JACOBS. Things change in 24 hours.

Dr. BRANDT. Yes, sir.

Chairman JACOBS. Thank you very much.

We will be back as shortly as we can.

[Recess.]

Chairman JACOBS. Our next panel is the American Society of Transplant Surgeons, Dr. Oscar Salvatierra, Dr. Norman Shumway, and Dr. Thomas Starzl.

Dr. Salvatierra, you may proceed, being the first on the list.

STATEMENT OF OSCAR SALVATIERRA, M.D., PRESIDENT, AMERICAN SOCIETY OF TRANSPLANT SURGEONS, PROFESSOR OF SURGERY AND UROLOGY, AND CHIEF, TRANSPLANT SERVICE, UNIVERSITY OF CALIFORNIA AT SAN FRANCISCO

Dr. SALVATIERRA. Mr. Chairman, we want to say at the outset how pleased we are to participate at these hearings.

It is our view that organ transplantation is entering a new era and that all of us should seek creative approaches to the variety of problems and challenges arising from our progress in this field. The bill before you today represents a significant contribution to the urgent resolution of a number of critical public health problems in the field.

The background of recent successes in organ transplantation is outlined in my written testimony. We are extremely gratified by the improved success of transplant procedures because of the increased number of patients who can now be restored to productive and fulfilling lives. New challenges lie in the need to provide an expanded base for the donation of organs and to make programs for procuring and distribution donated organs as efficient and effective as possible.

At the same time, we must also confront the very real problem of identifying financial resources to meet the cost of providing this technology to American citizens who might benefit from this therapy. We have carefully reviewed the provisions of H.R. 4080 as reported, and we are in strong support of the bill.

We would like to focus our attention first on those provisions which modify the existing medicare program. It is important to note in this context that this legislation does not establish a new entitlement program. Under the present statutory provisions, coverage of new procedures or therapies must be essentially universal, or coverage must be denied entirely. This so-called "all or none" policy has assured limited access to cardiac and liver transplants.

To be more specific, while HCFA has been sponsoring an experiment to evaluate further cardiac transplantation at a limited number of centers, under present interpretations of medicare coverage policy, it would not be possible to cover cardiac transplants unless they were essentially covered wherever they might be offered.

At this stage in the evolution of such therapies, we believe that it makes a good deal of sense to authorize medicare, on the advice

of expert medical opinion, the option of extending coverage initially on a limited basis to medicare eligible patients.

We believe that financing for nonrenal transplantation is a shared responsibility of public and private purchasers of health care. Medicare can advance the development of a public/private partnership by establishing a leadership role in the management of coverage decisions. Most importantly, it would eliminate the present inequitable access by patients to transplantation of those organs where appropriate reimbursement mechanisms do not exist.

In these cases, transplantation has often become dependent on public fund raising campaigns which favor the patient who has media appeal. I am submitting two articles for the record that clearly relate the strong economic and political considerations resulting in inequitable access to transplantation.

Unfortunately, therefore, the present reimbursement system makes it easier for most potential heart and liver recipients to be maintained in a reimbursable and costly critical ill-state until death than to be restored to normal life by the essentially nonreimbursable transplantation.

We would also like to address our strong support for the provision of the bill that would extend medicare coverage for outpatient self-administered immunosuppressive drugs during the 36-month period after organ transplantation.

The recent availability of cyclosporine has greatly enhanced our results in organ transplantation, and current 3 and 4 year followup studies clearly show a superiority over conventional therapy. We will be glad to discuss this later; it is outlined in my written testimony.

The cost of this drug therapy to the individual patients is high, but while cost to cover these drugs under medicare part B would increase, the actual costs associated with kidney transplant patients using cyclosporine would decline and result in a major cost savings to the medicare program. This cost savings would accrue from lower hospital use and from a lower use of dialysis, because more end stage renal disease patients could be transplanted, and the success of transplantation is improved.

No matter how you look at it, the removal of more patients from costly maintenance dialysis does result in major cost savings. Equally important is the fact that this provision would also eliminate the unethical need for an economics means test before a transplant is performed to ascertain whether a patient can receive a more expensive but better drug therapy such as cyclosporine.

Ironically, an equally expensive drug such ATGAM is fully reimbursed because the usual 2-week course of this drug is administered while the patient is in the hospital.

I should like to mention that the National Association of Patients on Hemodialysis and Transplantation is sending written testimony supporting this and other aspects of the bill.

A few words are in order regarding assistance for organ procurement organizations. As you are aware, the number of available organs can only be significantly increased by strong, local procurement agencies. A successful organ procurement agency must establish close linkage with the administrators and other health professional in community hospitals throughout its service area, thus in-

creasing the awareness of the need for donor organs and assisting in the necessary family counseling.

The grant provision of section 101 will be of great help in this area. Most importantly, this provision will also promote multiple organ donation. This was never universally considered until the recently improved success of nonrenal organ transplantation.

The funding provided by this provision is limited in amount and time, and we strongly support these limitations. Historically, we can look to the results of limited funding through the regional medical programs of approximately 12 years ago. They were responsible for the start and development of some of the currently better organ procurement agencies. We are confident that similar results will again be achieved.

In addition, new and different innovative methodologies will be tried and tested which could provide a sound framework for more efficient organ procurement efforts in the future.

In summary, Mr. Chairman, I would like to indicate that certainly the problems facing organ transplantation are not solely the responsibility of the Federal Government. The most important contribution of Federal legislation in this area is to provide leadership which can result in a more effective public/private partnership.

But be not mistaken, organ transplantation has developed to where it is, in good part, because it has been a Federal program in many of its aspects. We must make every effort to assure that the technology, which has made this country the world leader in the field of organ transplantation, because of Federal assistance, is available to our citizens for whom it is appropriate therapy.

To do less would be both ethically unacceptable, and uneconomical. Moreover, the price the potential transplant recipients pay while waiting for specific solutions to their critical problems is often too high—death instead of life.

I would like to thank you and the subcommittee for the opportunity to testify on this important legislation. We do want to continue our work with you and your staff to build understanding and support for this measure. Thank you.

[The prepared statement and newspaper articles submitted for the record follow:]

STATEMENT OF THE AMERICAN SOCIETY OF TRANSPLANT SURGEONS BY OSCAR SALVATIERRA, M.D., PRESIDENT AND PROFESSOR OF SURGERY AND UROLOGY, CHIEF, TRANSPLANT SERVICE, UNIVERSITY OF CALIFORNIA AT SAN FRANCISCO; NORMAN SHUMWAY, M.D., PROFESSOR AND CHAIRMAN, DEPARTMENT OF CARDIOVASCULAR SURGERY, STANFORD UNIVERSITY; AND TOM STARZL, M.D., PROFESSOR OF SURGERY, DIRECTOR, DIVISION OF TRANSPLANTATION, UNIVERSITY OF PITTSBURGH

SUMMARY

I. Background.—A brief overview is offered of advancements in organ transplantation highlighting the improved results obtained recently with the use of the new immunosuppressive drug, Cyclosporine. Also noted is the remarkable success with heart, heart-lung, and liver transplants. These advances underscore the need for an increased supply of donor organs and a more effective distribution system.

II. Medicare Amendments.—Particular attention is given to two amendments to the Medicare program. The Society supports a modification in the Medicare coverage policy process to grant additional discretion the Secretary of HHS to deal with Medicare coverage issues arising from advancements in medical care. In addition, the Society supports the amendment to extend Medicare coverage for outpatient immunosuppressive drugs during the 36-month period after organ transplantation. The

Society does not support a new entitlement program for extra-renal organ transplantation.

III. Assistance for Organ Procurement Agencies.—The Society supports the grant provisions of Section 101 of the bill which are designed to strengthen regional organ procurement agencies. These limited grants could aid in the establishment of integrated organ procurement agencies and in an expansion of the efforts of existing agencies.

IV. U.S. Transplantation Networks.—The Society supports the authority contained in Section 101 to support by contract a private entity to facilitate the distribution of organs among regions and to maintain a computer-based registry of individuals awaiting transplantation. It is important to note that this Network would work with area procurement agencies maintaining local autonomy in organ distribution.

V. Task Force on Organ Transplantation.—The Society endorses the appointment of a task force on organ transplantation to address the critical policy issues that exist in this area of medical care delivery. We believe this body should also continue in an advisory capacity to the administrative entity responsible for implementation of this legislation.

VI. Sale of Organs.—The Society strongly supports the provisions of Title III of the bill which prohibit the sale of human organs.

STATEMENT

Mr. Chairman, I am Oscar Salvatierra, M.D., Professor of Surgery and Urology and Chief of the Transplant Service at the University of California at San Francisco. I am here today representing the American Society of Transplant Surgeons in my current capacity as President of the Society. The Society includes over 300 surgeons specializing in organ transplantation across the nation. With me today is Dr. Norman Shumway, Professor and Chairman of the Department of Cardiovascular Surgery at Stanford University, and Dr. Tom Starzl, Professor of Surgery and Director of the Division of Transplantation at the University of Pittsburgh.

Our purpose today is to provide the Subcommittee with our views and recommendations concerning H.R. 4080 reported last November by the Committee on Energy and Commerce. We want to say at the outset how pleased we are to participate in these hearings. It is our view that organ transplantation is entering a new era and that all of us should seek creative approaches to the variety of problems and challenges arising from our progress in this field. The bill before you today represents a significant contribution to the urgent resolution of a number of critical public health problems in this field.

BACKGROUND

As with all scientific advancements, progress in organ transplantation is the product of many efforts by both researchers and clinicians. There has been a great deal of growth in our understanding of the body's immune system which has led to new approaches for managing organ rejection. The most notable example is the new drug Cyclosporine which has proved to be very effective in controlling the rejection process. Even more important than improvements in graft survival rates, Cyclosporine is responsible for a marked decrease in morbidity of the transplant recipient, which was attributable to moderate steroid doses with conventional immunosuppression. Specifically, Cyclosporine is responsible for a decrease in incidence and severity of infections and a decrease in incidence and severity of complications from conventional steroid therapy. Cyclosporine is thus uniquely responsible for the remarkable successes and the recent transition of heart, heart-lung and liver transplantation from experimental to therapeutic modalities. In kidney transplantation, Cyclosporine has not only resulted in improved kidney survival in most series, but it has resulted in earlier and greater rehabilitation of the transplant recipient.

We are extremely gratified by the improved success of transplant procedures and by the increased number of patients who can be restored to productive and fulfilling lives. However, these successes are now accentuating an already existing problem of an imbalance between the supply of and demand for transplantable organs. New challenges now lie in the need to provide an expanded base for the donation of organs and to make programs for procuring and distributing donated organs as efficient and effective as possible. At the same time, we must also confront the very real problem of identifying financial resources to meet the costs of providing this technology to American citizens who might benefit from this therapy.

We have carefully reviewed the provisions of H.R. 4080, as reported, and we are in strong support of the bill. We do have several minor recommendations to offer which we believe could further strengthen the measure.

MEDICARE AMENDMENTS

We would like to focus our attention first on those provisions which modify the existing Medicare program. It is important to note in this context that this legislation does not establish a new entitlement program. Eligibility for the Medicare program is not affected by any of the provisions contained in H.R. 4080.

There are two provisions in H.R. 4080 that we want to address in some detail. First, the modification to Medicare coverage policy in Section 201 and, second, the coverage of outpatient immunosuppressive drugs under Section 204.

In our opinion, the purpose of Section 201 of the bill is to provide additional discretion to the Secretary of HHS to manage the complex process of making decisions respecting Medicare coverage of advancements in medical care. Under the present statutory provisions, the Secretary has determined that coverage of new procedures or therapies must be essentially universal or coverage must be denied entirely. This so-called "all or none" policy has increasingly been strained as new technology or procedures have developed and have been made available at a limited number of sites for patients satisfying appropriate medical protocols.

In the field of organ transplantation, there are two recent examples. First, in the case of cardiac transplants, and, more recently, in the case of liver transplants. While HCFA has been sponsoring an experiment to evaluate further cardiac transplantation at a limited number of sites, under present interpretations of Medicare coverage policy, it would not be possible to cover cardiac transplants unless they were essentially covered wherever they might be offered. At this stage in the evolution of such therapies, we believe that it makes a great deal of sense to authorize Medicare, on the advice of expert medical opinion, the option of extending coverage initially on a limited basis. We are quite mindful of the need to make certain that any limited coverage decisions are, in fact, grounded on the experience and judgment of the medical specialists who develop and apply the therapy, and that such decisions are routinely reviewed and modified when appropriate.

Mr. Chairman, I do want to emphasize that we do not believe that a new entitlement program for extra-renal organ transplantation, analogous to the ESRD entitlement, should be added to the present Medicare program. What we support is a more orderly and rational process for coverage decisions. We believe ultimately that financing for extra-renal transplantation is a shared responsibility of public and private purchasers of health care. Medicare can advance the development of a public-private partnership by establishing a leadership role in the management of coverage decisions.

Most importantly, it would eliminate the present inequitable access by patients to transplantation of those organs where appropriate reimbursement mechanisms do not exist. In these cases, transplantation has often become dependent on public fundraising campaigns which favor the patient who has media appeal. Unfortunately, the present reimbursement system makes it financially easier for potential heart and liver recipients to be maintained during the course of their critical illness until death, rather than to be restored to normal life by the essentially uncovered transplantation service.

We would also like to address our strong support for the provision contained in Section 204 of the bill that would extend Medicare coverage for outpatient, self-administered immunosuppressive drugs during the 36-month period after organ transplantation. As we mentioned earlier, the recent availability of Cyclosporine has greatly enhanced our results in organ transplantation. The costs of this drug therapy to the individual patients is quite high, but we want to draw your attention to the cost analysis of this new coverage completed by the Congressional Budget Office (CBO).

The CBO estimates that, while costs to cover these drugs under Part B would increase, the costs associated with kidney transplant patients using Cyclosporine would decline. This decline results from lower hospital use and from a lower use of dialysis, because more ESRD patients could be transplanted and the success of transplantation is improved. In sum, the net effect would be a savings to the Medicare program. Most importantly, the social benefit would be tremendous, as many more American citizens would be returned to normal, productive lives. Equally important is the fact that this provision would also eliminate the need for an economic means test before a transplant to ascertain whether a patient can receive a more expensive, but better drug therapy such as Cyclosporine. Ironically, an equally ex-

pensive drug, known as ATGAM, is fully reimbursed because the usual two-week course of this drug is administered while the patient is in the hospital.

ASSISTANCE FOR ORGAN PROCUREMENT AGENCIES

As you know, effective regional programs for the procurement of donor organs are absolutely essential to the efficient and equitable operation of transplant programs. While some locations in the nation have effective organizations, many areas need help in establishing an organ procurement agency or in expanding the scope of operations in existing agencies. We all realize that the need for donor organs greatly exceeds the present supply, and this is expected to be more of a problem in the future. The number of available organs can only be significantly increased by strong regional organ procurement agencies.

Our experience suggests that, in most areas, a regional or local agency is the best model to assure a coordinated approach to the identification of donors and the appropriate distribution of organs. While there are a range of factors which influence the decision to be an organ donor, we know that a very large number of potential donors are never identified because of a lack of coordination and education of the health professionals managing the care of potential donors at the community hospital level. A successful organ procurement agency must establish close linkages with administrators, physicians, and other health professionals in community hospitals throughout its service area, thus increasing the awareness of the need for donor organs and assisting in the necessary family counseling.

Most importantly, this provision will promote multiple organ donation. This was never universally considered until the recently improved success of non-renal organ transplantation. However, a significant impediment towards achieving an operational multiple organ procurement system has been the lack of satisfactory funding for heart and liver procurement efforts. This provision should help to resolve some of these problems.

As the grant provisions in Section 101 of the bill are implemented, we believe it will be important to build carefully on the existing procurement system. As we noted above, in some areas, the existing agency may be performing well; but, a lack of resources has limited the scope of its area activities. In such instances, we believe support should be directed toward the existing agency rather than toward the establishment of a new entity without any previous experience. In those cases where there are presently multiple agencies, we believe the grant provisions could integrate all procurement activities within one agency that would work efficiently with all the area transplant centers.

Overall, we believe that organ procurement agencies should be evaluated in terms of their ability to assure:

- (1) quality control in surgical organ procurement;
- (2) quality control in organ preservation; and
- (3) equitable distribution of organs among participating transplant centers.

We also want to express our strong support for the provisions which permit existing agencies based in transplant centers to compete fairly with independent agencies for the grant support.

The funding provided by this provision is limited in amount and time, and we strongly support these limitations. Historically, we can look to the results of limited funding through the Regional Medical Programs of approximately 12 years ago. RMP grants were responsible for the start and development of some of our currently stronger organ procurement agencies. We are confident that similar results will again be achieved. In addition, new and different innovative methodologies will be tried and tested which could provide a sound framework for more efficient organ procurement efforts in the future.

U.S. TRANSPLANTATION NETWORK

Section 101 of the bill also includes provisions for the support of a private, national entity to facilitate the distribution of organs among regions and to maintain a registry of individuals needing organs. It is evident to us that, at present, there are gaps in inter-regional coordination of organ procurement activities and in the information system for organ distribution. In several regions of the country, there is efficient sharing of information concerning the need and the availability of organs for transplantation. However, we are concerned that some donated organs are not used because a suitable recipient was not identified within the region of origin, or that they are shipped out of the country because of difficulty in placing the organ somewhere else in the United States.

If there were a national information base, it would greatly facilitate organ distribution on an inter-regional basis. It would serve three primary purposes:

(1) It would facilitate placement of organs that cannot be utilized in the region of origin;

(2) It would better serve the needs of patients who require heart and liver transplantation where matching of donor with recipient size can be an important consideration; and

(3) it would facilitate matching of organs for a growing group of potential recipients who react adversely to most foreign tissues and who would otherwise be considered nearly untransplantable.

In order to best realize these goals, our Society has taken a formal position supporting a national computerized network. The federal financial support authorized in this bill would be essential to the maintenance of an accurate and timely computer-based information system on a national level.

There is one other aspect of this proposed national network which we wish to comment on further. We believe that it is important that an organ distribution system be based on the premise that local organ needs are the first priority, with regional and national availability of donated organs occurring when there is not a local need. We do not believe that it would be feasible or more equitable to centralize organ distribution within a national organization. We understand that this bill would retain local autonomy in organ distribution.

TASK FORCE ON ORGAN TRANSPLANTATION

Mr. Chairman, as you know, medical care delivery is changing rapidly. In our own specialty, advancements in transplantation and the technology that supports it have been extensive. We are acutely aware of the fact that we lack the answers to a growing number of critical questions. Therefore, we strongly endorse the appointment of a task force to assist in the identification of problems and to help fashion constructive approaches to the challenges we confront.

The need for a national task force on organ transplantation is underscored by the fact that this bill itself leaves unanswered some of the most vexing questions. For example, what is the most effective means of promoting multiple organ donation, and what measures can be taken to ensure that health care professionals are sensitized to the critical need for an increase in the supply of organs. Even more challenging, perhaps, is the matter of financing extra-renal organ transplants. Presently, there are large gaps in both public and private coverage of such procedures resulting in patients or their families having to resort to public appeals through the media. All of us would agree that this method of fundraising cannot result in equal access to this emerging therapy.

A final contribution which this task force could make is in the administration of this legislation. We believe that the administrative structure which is established to carry out the purposes of H.R. 4080 would benefit from having the advice and counsel of a national advisory group composed in a manner similar to the task force. In the course of their deliberations, we would hope the task force would consider the usefulness of a permanent advisory body to the Secretary of HHS to offer continuing expertise on these critical policy questions.

SALE OF ORGANS

Mr. Chairman, we have been appalled, as have you, with the recent proposals dealing with the sale of human organs. We want to state categorically our opposition to such schemes and our intention to discourage such activities. We strongly support the provisions in this bill which make it unlawful to engage in schemes for the sale of human organs. We would like to note that we have discussed this provision with some who believe a modification may be required to assure that those who unknowingly use an organ procured unlawfully are not liable for the sanctions imposed by this section. If we can assist with a clarification, we would be pleased to do so.

The existence of such schemes, however abhorrent, underscores the critical shortage of organs for transplantation. We are committed to supporting a variety of efforts to promote organ donation, to improve the efficiency and effectiveness of the organ distribution system, and to seek improvement of the skills applied to transplantation.

Certainly the problems facing organ transplantation are not solely the responsibility of the federal government. The most important contribution of federal legislation in this area is to provide leadership which can result in a more effective public-private partnership. We must make every effort to assure that the technology which

has made this country the world leader in the field of organ transplantation is available to our citizens for whom it is appropriate therapy. To do less would be both ethically unacceptable and uneconomical. Moreover, the price that potential transplant recipients pay while waiting for specific solutions to their problems is often too high—death instead of life.

Thank you for this opportunity to testify on this important legislation. We want to continue our work with you and your staff to build understanding and support for this measure. I will be glad to respond to any questions you or other members of this Subcommittee may have.

[From the Okland (Calif.) Tribune, Jan. 30, 1984]

TRANSPLANT SURGERY FOR THE AFFLUENT—PATIENTS DIE AWAITING ORGANS, FINANCIAL AID

(By Barbara L. Harris)

The baby has a fatal liver disease that slowly turns it into an emaciated, spider-like creature.

Its stomach is bloated, its skin a sickly yellow. Its arms and legs have no muscle and hang like the wasted limbs of a dying tree.

The disease is called biliary atresia. The baby has no bile ducts; its body takes no nourishment and barely grows.

Fluids accumulate in the abdomen, making it difficult for the child to breathe. Its organs are crushed. Blood backs up into the stomach, and when the veins can hold no more they rupture. The stomach bleeds.

Finally, like an old man who has washed down a fifth of cheap whiskey every day for 10 years, the baby develops cirrhosis in its liver. The liver is scarred and lumpy, its labyrinth of canals sealed forever.

TRANSPLANT NEEDED

Unless a healthy liver is found and transplanted in time, the baby will die.

Between 300 and 400 children are born with biliary atresia each year.

"More die waiting than we see in surgery," according to Dave Phillips, a spokesman for the University of Pittsburgh, which has performed two-thirds of all the liver transplants in the world.

Most often the baby dies before a suitable liver is found, or the family simply cannot come up with the \$100,000 down payment demanded by most hospitals before they will admit a transplant patient.

Insurance is little help.

In the eyes of most insurance companies and government medical assistance programs the operation is "experimental" and they refuse to pay for it.

FAMILIES PLEAD

Desperate families plead with politicians to bend the rules to save their babies. As a last resort, parents sacrifice privacy and dignity for a few seconds to rattle their tin cups, begging for help on the 6 o'clock news.

"It is a sad commentary that people have to do that kind of thing," said Dr. Charles Mittman, executive medical director of City of Hope Hospital in Los Angeles County.

"It's not a very rational way to allocate medical care."

Yet the sight of anguished parents driven to begging has become almost commonplace in a country where it seems that organ transplants are dispensed on the basis of who can afford them, who can mount the most effective public relations campaign, or who can catch the eye of a powerful politician.

"I think it is basic to our beliefs that every citizen have equal access to health care," said Dr. Oscar Salvatierra, chief of transplant surgery at the University of California Medical Center in San Francisco.

"This just flies right in the face of that."

5,600 TRANSPLANTS IN 1982

There were more than 5,600 heart, heart-lung, liver, kidney and pancreas transplants performed in the United States in 1982, the latest year for which total figures are available. The cost ranged from \$60,000 to \$250,000 apiece.

But if enough organ donors could be found, the Congressional Budget Office estimates, 10,000 kidneys could be transplanted each year, 12,000 to 75,000 people could be suitable heart transplant candidates, and 4,600 people in the final stage of liver disease could be eligible for transplants.

Adults who need liver, heart, heart-lung, pancreas or some bone marrow transplants face the toughest obstacles, unable to compete with "poster children" for the media attention it often takes to raise money for surgery.

"It's hard to amass a lot of sympathy for a 41-year-old man . . . who needs a new heart," said Roger Evans, a research scientist for the Battelle Human Affairs Research Institute in Seattle.

COMPLEX ISSUES

Doctors, patients, families, insurers and legislators look to the federal government for guidance, but the issues are complex and answers slow in coming.

People whose lives depend on organ transplants say state and federal officials and private insurance companies are more concerned about money than human lives, and continue to label transplants "experimental" just to get out of paying for them.

"It is ridiculous to have technology available that could save lives and then call it experimental and refuse to pay for it," said Felicia Lowe Schwartz, who helped organize Bay Area parents seeking expensive, experimental cancer treatments for their children after her daughter, Alana, was diagnosed as having cancer.

"Sophisticated technology has become a privilege of the affluent and not a right for everyone," Rick and Pat Escalambre of Concord said in a letter to President Reagan, after they raised \$250,000 for a bone marrow transplant for their daughter, Rachel. "Not every family can handle the emotional trauma of the disease, coupled with the financial demands."

Public policymakers, meanwhile, are uncertain whether transplants are "cures" or Band-Aids. They, and the medical community itself, are sharply divided over whether transplants have been used long enough to be judged safe and effective.

"When you get into a really serious illness where no established therapy works, and a patient's life is on the line, it is very difficult to keep in balance what works and what we wish would work," said Dr. Glen Caylor, a medical consultant with the California Department of Health Services.

Many doctors argue that if transplants are indeed experimental, federal research grants should include money to pay for patient care while a track record for the procedure is established. They also say a strong federal agency is needed to evaluate new treatments and procedures, like the Food and Drug Administration does for medicines and medical devices.

Instead, doctors say, federal money for clinical trials of new treatments and medical technology assessment has been cut.

Legislators and bureaucrats question whether replacing defective organs is the best use of dwindling public health care dollars when so many people still lack even the most basic levels of medical care.

FEAR OF DECIMATED COFFERS

They fear public funding of transplants will decimate already depleted state and federal coffers.

"There has been an explosion in transplant technology," Caylor said. "Unfortunately, technology is way out in front of our social, political and economic thinking on this."

The dramatic leap forward in transplant surgery came suddenly in December 1979 when doctors began using cyclosporine, a new immunosuppressant drug that keeps the patient's body from rejecting the newly implanted organ.

Until then most patients died within months after surgery from infection: they were too weak to withstand or because their bodies rejected the transplanted organs.

With cyclosporine, better tissue typing and new surgical techniques, however, patient survival soared, and surgeons began performing more transplants.

But the demand for human organs quickly outstripped the supply.

For every liver transplant doctors at the University of Pittsburgh were able to do last year, another patient died waiting. A third of Stanford University's heart transplant candidates die before a donor is found, and only half of those awaiting kidneys in this country get them.

NATIONAL NETWORK SOUGHT

Fewer than 10 percent of the organs available for transplant are actually donated, said U.S. Rep. Albert Gore Jr., D-Tenn., author of a bill to establish a national computerized network for procuring and distributing organs and tissues for transplant. Shortages are but part of the problem.

The nation's organ procurement system is highly fragmented, Gore found during hearings of the House Subcommittee on Health and the Environment in Washington, D.C. last April.

There are 110 organ procurement groups in the country, nearly twice as many as needed to operate efficiently, Dr. Jeffrey Prottas testified.

Communication between organ banks is infrequent, procurement groups are extremely protective of their territory and are geared to finding kidneys and corneas, the organ and tissue transplanted most often.

"Last year, 200 kidneys were shipped out of the country because it was easier to place them overseas than through domestic procurement channels," said Salvatierra of the UC Medical Center.

Even finding a suitable organ doesn't guarantee a transplant.

300 LIVERS UNUSED

At least 300 of the livers offered to the University of Pittsburgh for transplant last year were not used because and handful of doctors trained to perform the delicate operation were too busy to retrieve all of them, Gore said.

Even if more organs were found and distribution channels were improved, other barriers to transplantation remain.

"If the lack of organs doesn't limit the number of transplants, the lack of money will," said Evans, of the Battelle Institute.

At \$60,000 to \$250,000 apiece, organ transplants are clearly beyond the means of most people.

Lack of money nearly cost a 14-month-old Fresno girl with biliary atresia her chance for a new liver last year.

Her stomach distended, eyes and skin jaundiced, Koren Crosland was given but a few weeks to live.

California Medi-Cal and Children's Services, a state and federally funded relief fund for children with catastrophic illnesses, refused to pay for her liver transplant, and when a new liver was found in the middle of the night on July 27, the University of Minnesota Medical Center refused to admit Koren without a guarantee that her bills would be paid.

ELIGIBLE FOR MEDI-CAL

There was a flurry of predawn telephone calls, and at 5:30 a.m. Gov. Deukmejian declared liver transplants were no longer experimental for treatment of biliary atresia and were now eligible for Medi-Cal.

Without the governor's ruling, Koren probably would not have gotten the liver, said Donna Anderson, Minnesota's director of admissions.

After a frenetic week trying to get money for a liver transplant for a young Pacifica boy dying of the same liver disease, state Sen. Art Agnos, D-San Francisco, called the system a disgrace.

"People should not have to rely on the heroic intervention of politicians to save their lives," he declared.

Yet nearly two-thirds of Minnesota's liver transplant patients are denied coverage by government and private insurance, Anderson said, while other hospitals in the country estimate 15 percent of their transplant patients must resort to public fund-raising campaigns to pay for their care.

Liver, heart, heart-lung, pancreas and some bone-marrow transplants remain experimental, and the federal government and most insurance companies won't pay for them.

"Most states and insurance companies follow the lead of the federal government," Evans said.

SLOW TO TAKE STAND

And the federal government has been slow to take a stand on transplantation.

It pays for kidney transplants and dialysis under a special Medicare entitlement program for kidney patients. In its 12 years, the cost of the program has swelled from \$229 million a year to \$2 billion, and officials aren't eager to have history repeat itself.

Five years ago, Dr. Norman Shumway, the Stanford surgeon who performed the first heart transplant operation, asked Medicare to pay for heart transplants.

But not until 1982 did the Department of Health and Human Services finally commission a study on heart transplants. The study will be completed in June, Evans said.

A national study requested in 1982 to evaluate whether liver transplants are still experimental was completed last September, but the administration has not decided yet whether to allow Medicare and Medicaid coverage.

Doctors sensitive to the delays say people are dying while the federal officials ponder, and many people have grown cynical about the ad hoc system in which politicians occasionally step in to save the child who is fortunate enough to get their attention.

SELECTION DILEMMA

"Selecting who will live and who will die, on a random basis, is sort of like lining up 20 kids on a firing line, then giving someone 10 bullets and telling him to pick off any 10," said Steve Shear, a Bay Area lawyer who specializes in health issues.

What is needed, he said, is health care planning on a national level.

"The problem is that nobody really sets priorities. It's done on a very ad hoc level," he said.

LITTLE COMFORT FOR JENNIE WHILE LIFE EBBED AWAY

Jennie Milazzo was a spirited child with sparkling blue eyes, a glowing pink complexion and straight chestnut hair. She preferred people to toys and almost anything to the regimen of hospitals, doctors, needles, tubes and drugs that filled the last days of her life.

Just two weeks before her death last August, Jennie talked of starting kindergarten in the fall, riding the bus to school and sleeping in her own bed again.

"Cancer was not something that was really acceptable to her," said her mother.

"It was a sickness, a disease, that was never really part of her."

At 4½, the Santa Rosa girl, the eldest of Tony and Kathy Milazzo's three children, was diagnosed as having neuroblastoma, a fast-growing childhood cancer that kill roughly half of its victims within two years of diagnosis.

Jennie was a candidate for a bone marrow transplant at the University of California Medical Center in Los Angeles last summer, but a tumor was found in her abdomen the day doctors were to start post-transplant treatments, and within two weeks it was the size of a full-term baby in its mother's womb, Mrs. Milazzo said.

Her mother said she wishes now that they had taken Jennie for a bone marrow transplant immediately, instead of allowing doctors to try traditional chemotherapy that didn't work, and left Jennie weak and in pain.

"I would have gone for the transplant earlier," she said. "I wouldn't have put her through chemotherapy knowing it wouldn't work."

For Jennie, her mother said, as risky as the bone marrow transplant would be, "it represented an escape from the cancer."

Jennie stopped breathing in August when her respirator came unhooked while nurses at the UCLA hospital were moving her. Her mother told them not to revive her.

"I told them to let her go, if all they could do was bring her back for two or three weeks more of suffering," Mrs. Milazzo said. "She already suffered enough."

Throughout Jennie's illness, her parents struggled to keep their daughter's spirits up. But they found it difficult, and there was little outside help for a child so young.

"I guess she wasn't supposed to have those feelings," her mother said. "But she did. She was very, very angry."

Mrs. Milazzo said Jennie had been a cheerful child, giggly and precocious, always leading her younger brothers, Mark and Adam, on wildly creative escapades.

Unaccustomed to suffering, and confused about how much pain was supposed to be part of her life, Jennie began to grow fussy and withdrawn in the fall of 1982.

Later, she learned to ignore the pain, "as if wishing would make it so," her mother said.

In November 1982, doctors found a tumor in her abdomen, operated to remove it and began chemotherapy.

In June 1983, they found a second tumor and, last August, a third.

Cancer transformed the large, chubby-cheeked child into a tall, slender girl. Her straight brown hair fell out after chemotherapy, and the hair that grew back was blond and curly.

Jennie knew what most children did on hot summer afternoons while she was confined to a hospital bed in Los Angeles, her mother said, and it made her angry. "She kicked and screamed and fought and bit, and a lot of doctors and nurses didn't want to work with her," Mrs. Milazzo said.

"Yet when I looked, there was Jennie, the sweet little girl that I knew, laying in that bed."

On several occasions, Jennie ripped out the tube that tethered her to a respirator. Yet, throughout the difficult months of nightmares of death and excruciating pain eased by morphine, Mrs. Milazzo said, Jennie assured her parents she would make it through the bone marrow transplants, if only to allow her to go home again.

"I hate L.A. I hate the people and I hate the cars, . . ." she told her parents.

She wanted to go home, she said, "but I don't want to die."

And though her parents sought help in dealing with the emotional trauma of painful surgery and chemotherapy that made her sick, they found nothing they could afford.

Instead, Milazzo, a machinist in San Rafael, and his wife, a sales clerk, took leaves from their jobs, packed up the family and moved to Los Angeles to be with Jennie.

There was always someone with her, playing games, listening to music, tape recording her voice, and in the last days, just holding her hand.

Mrs. Milazzo said she now wishes the family could have afforded to hire a private therapist to make the end a little easier for Jennie.

"There wasn't much available to help her cope with her anger," she said.

[From the Oakland (Calif.) Tribune, Feb. 2, 1984]

TRANSPLANT TOO COSTLY? TRY POLITICS—FRIEND IN WHITE HOUSE CRUCIAL TO SAVING MANY

(By Barbara L. Harris)

If your child were dying and needed a liver transplant to survive, would you:

- (A) Call the doctor?
- (B) Call the insurance company?
- (C) Call the White House?

Strange as it might sound, a growing number of parents have found that a powerful politician is as crucial to the medical team as doctors, nurses and health insurers when someone is stricken with a catastrophic illness and needs an organ transplant to survive.

In the absence of comprehensive state or federal policies on who should get organ transplants and who should pay for them, a well-connected politician can bend the rules and rewrite regulations to save the patient who seeks his help.

But for every person the politicians are able to help, they conceded that many more people probably go unaided.

"It's like putting out forest fires," said Roger Evans, a research scientist for Battelle Human Affairs Research Institute in Seattle.

FOCUS AND RESPONSE

"The press focuses on one case, and the president responds to it," he said.

"Saying 'We're doing something,' takes them off the hook."

In one of the most widely publicized cases, President Reagan made a dramatic plea for a human liver to save 11-month-old Ashley Bailey of Texas.

"She is now fed intravenously," Reagan said on radio in June, "and has but two or three weeks to live unless she receives a liver transplant. 'Time is running out.'"

Time was also running out for 2-year-old Adriane Broderick, who had biliary atresia, the same fatal liver disease as Ashley.

But a month after his plea for Ashley, President Reagan backed a ruling by the Department of Defense in which it refused to pay for Adriane's liver transplant under its CHAMPUS health insurance for dependents of military personnel.

IT'S EXPERIMENTAL

"... it is legally objectional to pay for experimental medicines and surgery, until such time that medical researchers prove that a therapy is effective and that it is not more likely to harm the patient than to help," the Defense Department told Adriane's mother and father, a captain in the Army in Louisiana.

Yet without a new liver, Adriane had no chance of surviving. Congress hurried, ordering CHAMPUS to pay for liver transplants, but Adriane died of complications following surgery.

A suitable liver was never found for Ashley, and she died in November.

"Sure, it's politics of the first order," presidential aide Michael Batten conceded.

"It's whoever can get to the White House, whoever can use the media."

Batten was hired by the president to work in the White House Public Liaison Office with families who seek the help of the president and first lady in obtaining organs and money for transplant surgery.

BETTER THAN NOTHING

He calls his office "the body shop" and human organ banks "giblet-gravy groups," and he defends the president's case-by-case approach as better than nothing until a better way is found to hand out organs and money to pay for their transplantation.

"We aren't going to sit around and wait for policy," he said.

Nor is the administration likely to set it, relying instead on the private sector and individual states to decide what procedures should be financed.

Instead, Batten is the administration's arm-twister, using "the good offices of the president" to get states and private insurance carriers to do what the federal government will not: pay for surgery it classifies as experimental and, therefore, ineligible for coverage under most of its medical assistance programs.

"When we come in, we make 'em look like dogs," Batten boasted.

"They always knuckle under."

"On behalf of the president, Batten urged the Texas Legislature to pass a bill appropriating \$41,000 for Ashley Bailey's transplant, although that state's constitution prohibits earmarking public money for a particular person.

MATCHING MONEY

"What we tell people is that if a state will pay, we stand ready to commit our half of the (Medicaid) money," he said. This places the burden on each state. In Ashley's case, the federal matching money to \$62,000, which would have gone to the state if she had received a new liver.

Last year Batten also commandeered a military jet to fly a little boy from Utah to Tennessee for a liver transplant.

Air Force officials balked at first, but Batten urged: "Do this one for the gipper." They did.

President Reagan and the U.S. Department of Health and Human Services still have not made a decision on whether liver transplants should be removed from the experimental list, although a massive federal study on the issue was completed before Labor Day.

An HHS spokesman speculated that new Secretary of health Margaret Heckler might need more time to analyze the lengthy report, or that the president has been too swamped with other issues to deal with it.

Although few people under the federal Medicare program would qualify for liver transplants, primarily because of their age, states and private insurers are looking to the federal government for a sound evaluation of the fledging technology.

OTHER EFFORTS

Batten is not alone in his efforts to hack out a means for people to get advanced medical care.

In California last summer, Gov. Deukmejian rewrote state Medi-Cal regulations from his bed at 5:30 in the morning so that Koren Crosland, a Fresno girl dying of biliary atresia, could have a liver transplanted after the University of Minnesota Medical Center refused to admit her without a guarantee her bills would be paid.

Nine days later, that new liver transplant policy was revised to allow the state to pay for a liver transplant at the University of California Davis Medical Center, although the hospital did not meet the state's criteria for liver transplant centers.

"It is very clear that the questions are not being addressed in an expert, organized fashion," said Dr. Charles Mittman, executive medical director of the City of Hope Hospital in Duarte, in Los Angeles County.

"They are largely spur of the moment and politically motivated."

ALTERNATIVE TO BEGGING

The increasingly common sight of families begging for money to pay for transplants has stirred fierce debate among government officials on the need to find a

more even-handed way to see that all people who need transplants get them, no matter how rich, poor, articulate or well-connected they are.

"It's up to us as leaders to find a better system," declared state Sen. Art Agnos, D-San Francisco, after a week of scrambling to see that a young Pacifica boy received a liver transplant.

The paradox is that some of the same politicians who bend the rules to help a single child are responsible for gutting programs that could help all those awaiting transplants.

Public spending on medical care for the poor, disabled and elderly has been cut severely in the past few years, while the cost of medical care is rising 12 to 15 percent a year.

The Reagan administration recommended a mere 1.8 percent increase in the 1984 budget for the National Institutes of Health, which amounts to no increase at all after inflation, and, in 1981, scrapped a \$4 million program to evaluate emerging medical technology and make recommendations whether the government should pay for such procedures.

EVALUATIONS MADE

A study by Harvard University and UCLA showed that the center evaluated 75 medical procedures and saved the government up to \$10 billion by recommending it not pay for several that the center said were worthless.

But the Reagan administration saw the agency as another unnecessary layer of government that accomplished nothing in its three-year existence.

In addition, many doctors fear that the lack of federal backing for medical research is slowing the development of new techniques that offer hope to people who might otherwise die.

"There are all these exciting things going on in medicine, but federal research funds are being cut or leveled off," said Mittman, of City of Hope Hospital.

"What we've got to do is jack up the private insurance industry (and) the university hospitals to do research and not to come to the government for funding," Batten responds.

"If they don't get it from the federal government, then they will get it somewhere else."

IT'S TOO IMPORTANT

But many doctors say health care is too important to be left to the vagaries of profit-making companies, and fear that new cures will be slow to develop without a strong federal commitment to medical research.

"There's plenty of money to perfect (transplants) on mice and rats, but when it's ready for people, they don't have the money for it," declared Rick Escalambre of Concord, who had to mount a huge media blitz last year to raise \$250,000 for a bone marrow transplant for his daughter Rachel, who was suffering from neuroblastoma, a deadly childhood cancer.

"We have the ability to develop the technology, but we have real difficulty making it available to our citizens," said Dr. Oscar Salvatierra, chief of transplantation at the University of California Medical Center in San Francisco.

Salvatierra said some of the federal government's reluctance to pay for organ transplants under Medicare, Medicaid and military medical programs is its own dismal track record with the End-Stage Renal Program, which guarantees dialysis treatments and kidney transplants to anyone who needs them.

When the program began in 1972, it served 11,000 people at a cost of \$229 million. Ten years later, there are 65,000 people in the program at a cost of nearly \$2 billion, and the price tag keeps growing.

Money is also on the minds of doctors and policymakers, who say it is difficult to justify spending \$100,000 to save the life of one transplant recipient, when the same amount of money could buy basic medical care for thousands of poor, disabled and elderly people.

"If we are going to pay for transplants, someone else is going to go without care," declared Dr. Esmond Smith, director of California Children's Services. CCS is a joint state and federal program that pays the medical bills of children stricken with catastrophic illnesses.

"I don't think we should commit ourselves to paying for any new technology without finding a permanent source of funding."

The present patchwork approach to organ transplantation has stirred fierce debate in Washington, D.C., over what the government's role ought to be, with some con-

gressmen pushing for strong federal leadership, while the administration is looking to the private sector for answers.

Late last year, President Reagan directed the Surgeon General to organize the American Council on Transplantation, a private federation of organ banks, hospitals, tissue typers and transplant physicians and surgeons to improve the organ procurement system.

MORE IMMEDIATE SOLUTIONS

The council's goal is to bring these organizations together to increase the number of organs donated, educate doctors and nurses about procuring organs for transplantation, and study ethical and financial problems related to transplant.

But last week, professional organizations representing many of the key participants boycotted the council's first meeting, saying the administration is using ACT to block proposed legislation that many feel would bring more immediate solutions to the transplant crisis.

"ACT is off in a different world," said Dr. Charles Carpenter, who heads the American Society of Transplant Physicians. He said 300 organizations were invited to be members, but only a small fraction are directly involved with transplantation.

"Maybe this is nothing but a show."

While ACT can be useful in educating the public about organ donations, he said it cannot answer questions of who will pay for surgery.

A bill by U.S. Rep. Albert Gore, D-Tenn., would address the payment issue, improve the procurement system and make other changes that Carpenter and other doctors feel are needed to make technology available to all who need it.

Chairman JACOBS. Thank you, sir.

Dr. Shumway.

STATEMENT OF NORMAN SHUMWAY, M.D., PROFESSOR AND CHAIRMAN, DEPARTMENT OF CARDIOVASCULAR SURGERY, STANFORD UNIVERSITY, ON BEHALF OF AMERICAN SOCIETY OF TRANSPLANT SURGEONS

Dr. SHUMWAY. My principal objective will be to bring you up to date on heart transplantation and heart-lung transplantation at the Stanford Medical Center.

As we know and has been said, tremendous progress has been made in this science and practice of transplantation during the past 10 years, and new drugs are available to control the immune response. Since we began the use of cyclosporine in December of 1980 at Stanford, there has been a significant reduction of clinical diagnosable rejection of allografted or transplanted heart.

There are some serious side effects, which Dr. Brandt alluded to, with cyclosporine, principally related, interestingly enough, to renal function, but the drug can now be synthesized, and it is really just the first drug of a family of drugs that will be developed and, therefore, we feel in future sister compounds its nephrotoxic properties will probably be deleted.

The developing technology for organ preservation has greatly widened the pool of donors as well. Hearts can now be transported up to 2,000 miles with every expectation that the transplant will perform satisfactorily immediately. Further work is progressing nicely in this area of research, and this has been funded generously by the Federal Government. Certainly the day will come when hearts can be preserved to the same temporal limits as liver and renal grafts.

Last year at Stanford University 39 heart transplants were performed, and seven heart-lung transplants. The 1-year survival rate now stands at 88 percent, and fully 90 percent of all patients

having heart transplantation at Stanford leave the hospital in stable condition. This statistics contrasts markedly with the 22 percent 1-year survival 16 years ago, the first year of clinical heart transplantation at Stanford University.

One hundred and twenty-one of the 288 patients undergoing heart transplantation during the first 16 years of the program at Stanford are living from one month to 14 years following the procedure. There were 155 one-year survivors.

Suffice it to say now that transplantation of the heart is on the same therapeutic footing as kidney transplantation. Medical centers in the United States and all over the world are reentering the field after a hiatus of almost 15 years. The number of heart transplants this year should at least double last year's total, with further expansion during the next decade.

The hospital costs for a patient having heart transplantation is roughly two to three times that for a standard open heart surgical procedure. To this date, no professional fees have ever been charged for any transplantation procedures at Stanford, either heart or heart-lung. Donor costs average \$3,000 and are independent of whether the donor is an onsite donor or in another hospital.

In the past, transplantation of the lung, of pulmonary tissue, has produced the most dismal results of any kind of organ transplantation. Of 38 unilateral lung transplants, no patient has lived as long as 10 months, and most patients died within a few days to a few weeks after the procedure. Only two patients, in fact, were ever discharged from the hospital.

Currently at Stanford, 12 out of 17 patients having transplantation of both lungs with the heart are alive and well, out of the hospital, fully rehabilitated 1 month to almost 3 years after the transplant, the first one being done on March 9, 1981. This complete turnaround in clinical results derives from the concept of using the heart as the monitor of immunologic events surrounding the transplanted cardiopulmonary axis.

Actual biopsy of the heart reveals precisely the status of the lungs with respect to the host's immune reactivity, since the heart and lungs are rejected *pari passu*. Since X-rays are very much in doubt, this precise information is tremendously important.

Irrespective of any conceivable advance in artificial organs, heart-lung transplantation is here to stay. The concept of a totally implantable artificial heart with an inexhaustible, noiseless, non-heat producing energy source is one that must be respected and sought, but its realization is at least decades away. Anything man-made that could substitute for the entire cardiopulmonary axis is beyond conceptualization.

The early clinical results of heart-lung transplantation were so gratifying that other centers have started programs and others still are almost certain to develop in this field. Approximately 30 such transplants have now been done worldwide, and next year should see, perhaps, another 50.

At the outset of heart transplantation 16 years ago, many potential heart donors were lost owing to medical and nursing neglect. Through various educational programs and seminars where the results of heart transplants, and kidneys, too, were discussed, inten-

sive care units in most hospitals began to make the necessary maneuvers to keep organs in transplantable condition.

The heart is the most prodigious consumer of oxygen of any organ in the body, so its care in the potential donor must be precise and thorough. Lungs are even more delicate and more difficult to maintain in transplantable health. Teaching programs are now just starting in the San Francisco Bay area to acquaint intensive care unit personnel in certain key hospitals with the essentials of pulmonary care in the potential heart-lung donor.

The usual wait by a patient for a heart donor is no more than a few weeks, but the delay for an adequate lung donor is much longer. We hope to improve this situation by outreach training programs for intensive care unit personnel.

In summary, then, transplantation of the heart, we feel, is a proven therapeutic intervention with a 5-year survival rate of at least 50 percent and a 1-year of 88 percent. While there may be some future application for the artificial heart as an interim device before transplantation, there is no such mechanical substitute for the lungs, and the early results of transplantation of the heart along with both lungs are even better than for transplantation of the heart alone.

That concludes the statement, and I will be glad to answer any questions.

[The prepared statement follows:]

STATEMENT OF NORMAN SHUMWAY, M.D., PH.D., PROFESSOR AND CHAIRMAN,
DEPARTMENT OF CARDIOVASCULAR SURGERY, STANFORD UNIVERSITY

HEART AND HEART-LUNG TRANSPLANTATION

Tremendous progress has been made in the science and practice of transplantation during the past ten years. New drugs have become available to control more effectively the immune response to transplanted tissue. Since we began the use of cyclosporine in December of 1980 at Stanford University, there has been a significant reduction of clinically diagnosable rejection of the allografted heart. There are some serious side effects with cyclosporine, principally related to renal function, but the drug can now be synthesized, and its nephrotoxic properties should soon be deleted from sister compounds.

The developing technology for organ preservation has greatly widened the pool of donors. Hearts can now be transported up to 2,000 miles with every expectation that the transplant will perform satisfactorily-immediately. Further work is progressing nicely in this area of research, and the day will almost certainly come when hearts can be preserved to the same temporal limits as renal and liver grafts. Last year at Stanford University, 39 heart transplants were performed on 37 patients. The one-year survival rate now stands at 88 percent, and fully 90 percent of all patients having heart transplantation at Stanford leave the hospital in stable condition. This statistic contrasts markedly with the 22 percent, one-year survival sixteen years ago, the first year of clinical heart transplantation at Stanford University. One hundred and twenty-one of the 288 patients undergoing cardiac transplantation during the first 16 years of the program at Stanford are living from one month to fourteen years following the procedure. There were 155 one-year survivors. Suffice it to say that transplantation of the heart is now on the same therapeutic footing as kidney transplantation. Medical centers in the United States and all over the world are re-entering the field. The number of heart transplants this year should at least double last year's total, with further expansion to be expected later in the decade.

The hospital cost for a patient having heart transplantation at Stanford is roughly two to three times that for a standard open heart surgical procedure. To this date no professional fees have ever been charged for any transplantation procedure at Stanford, either heart or heart-lung. Donor costs average \$3,000 and are independent of whether the donor is an on-site donor or in another hospital.

In the past, transplantation of the lung, of pulmonary tissue, has produced the most dismal results of any kind of organ transplantation. Of 38 unilateral lung transplants no patient lived as long as ten months, and most patients died within a few days to a few weeks after the procedure. Only two patients were ever out of the hospital. Currently at Stanford, twelve of seventeen patients having transplantation of both lungs along with the heart are alive and well, out of the hospital and fully rehabilitated one month to almost three years after the transplant. This complete turnaround in clinical results derives from the concept of using the heart as the monitor of immunologic events surrounding the transplanted cardiopulmonary axis. Actual biopsy of the heart reveals precisely the status of the lungs with respect to the host's immune reactivity, since the heart and lungs are rejected *pari passu*.

Irrespective of any conceivable advance in artificial organs, heart-lung transplantation is here to stay. The concept of a totally implantable artificial heart with an inexhaustible, noiseless, non-heat-producing energy source is one that must be respected and sought, but its realization is decades away. Anything man-made that could substitute for the entire cardiopulmonary axis is simply beyond conceptualization. The early clinical results of heart-lung transplantation are so gratifying that other centers are almost certain to develop their own programs. Approximately thirty such transplants have now been done worldwide, and next year will see perhaps another fifty.

At the outset of heart transplantation, sixteen years ago, many potential heart donors were lost owing to medical and nursing neglect. Through various educational programs and seminars where the results of transplantation of the heart, and of kidneys too, were discussed, intensive care units in most hospitals began to make the necessary maneuvers to keep organs in transplantable condition. The heart is the most prodigious consumer of oxygen of any organ in the body, so its care in the potential donor must be precise and thorough. Lungs are even more difficult to maintain in transplantable health. Teaching programs are now just starting in the San Francisco Bay area to acquaint intensive care unit personnel in certain key hospitals with the essentials of pulmonary care in the potential heart-lung donor.

The usual wait by a patient for a heart donor is no more than a few weeks. The delay for an adequate heart-lung donor is much longer, but we hope to improve the situation by our outreach training program for intensive care unit personnel.

In summary, then, transplantation of the heart is a proven therapeutic intervention with a five-year survival of at least 50% and a one-year survival of 88%. While there may be some future application for the artificial heart as an interim device before transplantation, there is no such mechanical substitute for the lungs, and the early results of transplantation of the heart along with both lungs are even better than for transplantation for the heart alone.

Chairman JACOBS. Thank you, sir.

I want to thank both of you. I have only noticed what I overlooked before, there is virtually a second page of witnesses, and those people are going to be here pretty late. So thank you very much for the conciseness of your testimony.

Dr. Starzl.

STATEMENT OF THOMAS STARZL, M.D., PROFESSOR OF SURGERY, AND DIRECTOR, TRANSPLANTATION DIVISION, UNIVERSITY OF PITTSBURGH, ON BEHALF OF THE AMERICAN SOCIETY OF TRANSPLANT SURGEONS

Dr. STARZL. Thank you, Mr. Jacobs.

My testimony reiterates so closely what you have already heard that I won't bother reading it, but I would like to submit it for the record.

Chairman JACOBS. Without objection.

Dr. STARZL. Instead, if you would permit me to comment extemporaneously on some of the testimony that has already gone forward. It is obvious from hearing Dr. Brandt especially, and also Dr. Davis, that there is a good deal of kindness in their attitude toward their constituency needing health care, but they have bluntly stated their conclusion which is that they are against this bill.

I, therefore, would like to bluntly state mine and that is, I think it is a very fine bill and I hope it passes. I think that it would do wonderful things for health care in this country. It would clearly increase the organ supply. It would provide better care practices. One of the most important provisions of the bill would represent a radical departure from previous practice, as Dr. Davis has said, and that is to pay for drugs.

The way the system works now, the end stage renal disease program has become fantastically expensive and perhaps this is a good time to consider some creative administration, and consider that with the use of better drugs, or even for that matter paying for old-time drugs, there might be an incentive to move patients from the very expensive dialysis into the transplant programs. I think that that is a tremendously important provision of this bill, and I hope it passes.

Finally, Dr. Shumway didn't openly state it, but the problem that he has encountered, and other people interested in heart transplantation, has been the Federal Government itself, which has pronounced procedures such as heart and heart-lung transplantation or, for that matter, liver transplantation to be experimental. This was not a pronouncement of the present administration, this goes back several administrations before.

Once that kind of jargon gets into the debate about things like cardiac or liver transplantation, it is very difficult to get it out. Then the Government serves, by its nomenclature, as almost as an excuse, or a shield to prevent third party insurance carriers from paying for the procedure, because they ask, if the medicare says that it is experimental, should we pay for procedures such as heart transplantation. It is a kind of a dodge, I think, and the bill squarely addresses it in one of its provisions.

There has been a lot of philosophical discussion this morning about how important it is for the private sector to be respected in its rights, and I would like to comment on that just in one or two details.

It is said that the donor program is a private agency and now should be allowed to continue to function. Yet, the entire donor program in the United States is federally funded. It is part of the Social Security Act of 1973. I have also heard it said this morning that the kidney transplant program in the United States represents a benchmark of private enterprise, but those are also entirely federally funded. I just can't see that they represent an advertisement for private enterprise in medicine, because they are paid for by the Government.

Thank you.

[The prepared statement follows:]

STATEMENT OF THOMAS STARZL, M.D., PROFESSOR OF SURGERY, AND DIRECTOR,
TRANSPLANTATION DIVISION, UNIVERSITY OF PITTSBURGH

The bill under consideration today would have a major impact in applying the great advances in transplantation for the treatment of patients with failure of a single vital organ system. The legislation should increase the supply of organs and would remove a number of economic barriers which have imposed great hardships on the patients and their families. I would like to speak to 2 specific issues; both of these concern policies of the Social Security system.

The first is the legislative mandate that medications for endstage renal disease patients may be provided only during the period of hospitalization, but not thereafter. Even when this policy was initiated in 1973, it created significant problems for patients who needed a supply of the drug azathioprine, as well as prednisone. Now, the most effective immunosuppressive drug available (cyclosporine) is even more expensive, and it is estimated that the cost of this drug for the first postoperative year will be about \$5,000 per adult patient. Many recipients do not have this kind of money, and may be forced to undergo transplantation with less than optimal drug therapy purely for economic considerations.

The irony of the situation is that the cost of performing cadaver renal transplantation with inferior results under old time immunosuppression is far greater than with the new drug combination of cyclosporine and steroids. Studies done at our institution, Ohio State, and the University of Minnesota, have all shown about a 40% savings with the single expedient of using cyclosporine. This adds up in any given case to a \$10,000 or \$15,000 savings in the first year. In human terms, the losses are even less acceptable since the results in our experience and that of several other groups have been superior with cyclosporine. In a randomized trial at the University of Pittsburgh, the one-year kidney graft survival was almost doubled with cyclosporine therapy, and the same thing has been seen in liver and heart recipients.

Dr. Salvatierra asked me to come here today to speak about cyclosporine and its importance, largely because of the perspective which I can provide about the role of this agent in permitting better medical services. In the past, the forms of treatment that could be provided were with 2 drugs called azathioprine and prednisone (double-drug therapy), or with the triple-drug combination of azathioprine, prednisone and a substance called antilymphocyte globulin (ALG). I introduced both of these so-called conventional forms of treatment; the first 22 years ago and the second 18 years ago. No one knows better than I do the dangers and morbidity associated with these forms of therapy and thus no one can contrast better the remarkably improved convalescence that can be seen today with cyclosporine-steroid therapy. If we do not make some provision to pay for these new medications, we will permit transplantation of all organs to be far more expensive than is necessary, and worse than that, force the use of suboptimal regimens of care.

The second appeal which I am making also concerns the medicare arm of the Social Security system. For a number of years, the position of federal agencies has been that transplantation of the liver and the heart are experimental procedures and thus not fundable by conventional medicare-medicaid mechanisms. The number of potential cardiac and liver recipients who have had the necessary 2 years of invalidism to qualify for medicare reimbursement was a very small one. However, the declarations by federal agencies about the experimental nature of the procedure has been used by many insurance companies as an excuse to avoid meeting their obligations to their clients. "After all", they have reasoned, "why should we pay for liver or heart transplantation when the government has pronounced these operations experimental?" The result has been that in order to realize the very small cost containment within the medicare system, made possible by the experimental pretext, third-party insurance carriers have been provided with an open invitation to use the same excuse to avoid their obligation.

Realizing the problem, a number of federal agencies including the Surgeon General's office, NIH and HCFA conducted what is known as a Consensus Development Conference last June in Bethesda, Maryland, on liver transplantation. The conclusion from the deliberations was that liver transplantation was not only a service (as opposed to an experimental undertaking), but that in many disease entities it was the only reasonable form of service that could be provided. I am sorry to say that in spite of this conclusion, the Consensus Development document which will be published in a major journal within a month or so has not yet been officially released from HHS. The provisions of the law under consideration today would eliminate this roadblock. I would emphasize that passage of the bill would not be an entitlement clause to the Social Security system, but would merely make it clear that procedures such as liver and heart transplantation are bona fide therapy.

Chairman JACOBS. Thank you.

Mr. Moore.

Mr. MOORE. Mr. Chairman, very briefly, any one of the physicians who might want to answer this. We have heard considerable praise, much of it, I am sure, quite justified on the new drugs like cyclosporine. I understand, however, that Dr. VanderWerf of the Phoenix Transplant Center has some commented that he is not so

sure that the drug is necessary, especially if there was better sharing between different centers and also better DR matching.

I am not sure that I understand all of that. Is there some truth to what he is saying in your professional opinion?

Dr. STARZL. I think I can answer that. It is relatively small, but it is a good program located in Phoenix, run by Dr. VanderWerf and one of my former associates and trainees. It is a partnership, and it is one of the few private groups that is entering into liver transplantation.

As to their comments about DR matching, that is a concept that in the United States, in large collected series, has not really held up. I think you can see in small series of patients who are very heavily transfused an increase in graft survival under conventional immunosuppression. This is true. But all of us, and Oscar, I am sure, will concur in this, would like to see those practices of preoperative transfusion stopped because they sensitize about a third of the patients and they contribute to this growing list of people who are stacked up on dialysis units.

On the cyclosporine trials, transfusion does not seem to be necessary. Even that aspect of it, avoiding the transfusion under the best immunosuppression available today, allows more patients to be treated with transplantation at a reduction in cost.

I think that Dr. VanderWerf's comments, while they are not untruthful, are basically without merit.

Dr. SALVATIERRA. I think this needs a little further comment. What cyclosporine has really allowed, and I will contrast that with conventional therapy—what cyclosporine has really allowed is early transplantation of the patient needing that therapy.

Most series have shown improved graft survival, but most importantly what cyclosporine has done, it has provided for a decrease in the incidence and severity of infections, and a decrease in the incidence and severity of complications from steroid therapy which is a part of conventional therapy. In other words, the patient sustains less morbidity. It is a better patient. The cyclosporine patient is a patient who is rehabilitated much sooner after the transplantation.

With conventional therapy, not only are we dealing with steroid and other drugs, but we are dealing with other procedures as part of the transplantation which can prolong that patient's period of dialysis, and therefore potentially make him more unacceptable as a transplant recipient later on. And this refers to the areas that Dr. Starzl alluded to, the sensitization, the blood transfusions, also the practice of splenectomy, and so forth. The wait for a DR match kidney is a costly process and can make the patient potentially untransplantable.

There are real differences between what is considered under conventional therapy, what is considered under cyclosporine therapy in these outcomes, and these outcomes are more than just a consideration of graft survival.

Mr. MOORE. Mr. Chairman, I would like to introduce into the record at this point, if I could, a letter to Congressman McCain dated December 29, 1983, from Dr. VanderWerf. This is simply for the record, at this point, since we are talking about his comments which are explained further in the letter. I don't see any point with me dealing any further with them at this time.

Chairman JACOBS. Without objection.
[The letter from Dr. VanderWerf follows:]

GOOD SAMARITAN MEDICAL CENTER,
PHOENIX TRANSPLANT CENTER,
Phoenix, Ariz., December 29, 1983.

Hon. JOHN MCCAIN,
U.S. House of Representatives,
Longworth Building, Washington, D.C.

DEAR REPRESENTATIVE MCCAIN: I have received several responses to my previous correspondence to you dated November 8, 1983 in reference to a proposed National Organ Transplant Act, H.R. 4080, and particularly Title III.

I am happy to hear that my original concern has been acted upon so that compensation for reasonable costs associated with organ donation from related and non-related donors for non-commercial reasons, can still be made.

In reading through the Committee Report, I would like to make some additional comments.

1. There is a tremendous amount of emphasis put on the new drug, Cyclosporin A, which gives much better transplant results if you start off with a very low yield. During the last three years, we have limited our cadaver donor transplants to so called DR matched transplants. Our results are at least as good as centers have reported using Cyclosporin. The extensive and continuing efforts of the staff of the Phoenix Transplant Center and myself have resulted in an ample supply of cadaver donors and kidneys. Many of our donors have also provided hearts for transplant at Tucson and Stanford and a few livers were sent to Pittsburgh and Minnesota.

If organs could be shared properly between different centers, there is no need for the very expensive Cyclosporin drug because the same results can be accomplished by DR matching.

It still needs to be seen if we could further improve with the use of Cyclosporin, but we expect this would have a very limited impact. The DR matching is not something that we discovered, but our contribution to DR matching has been that as a single center, only using the UNOS computer system for sharing, we have been able to show that all local transplants can be done with DR matching, as well as providing the majority of kidneys that we send out, to DR matched patients at other centers. Obviously, if more centers would participate in such a sharing program, it would be accomplished much easier on a large scale. One of the main obstacles is that most centers do not want to share their kidneys if better matched patients are available at other centers. The bottom line is, will our government choose the expensive solution of Cyclosporin or a much cheaper system which is equally good, i.e., DR-matching but with curtailed freedom for the transplant centers on the use of kidneys from their cadaver donors? We have reported extensively on our results at the American Society of Nephrology in December 1982, as well as at the American Society of Transplant Surgeons in Chicago in June, 1983.

2. If payments are felt to be necessary for immunosuppressive drugs, I would prefer that this would be included in the DRG payments so that every center will have the freedom to utilize them and do what they feel is the best for their patients.

If you would be interested in more specific information about our program, I could refer you to the Network VI Review that was just completed and that has compared our local results with other centers in the Network VI area. Also, I would be more than willing to appear for the Committee to testify as well as send additional information as requested.

Thank you very much for your attention.

Sincerely yours,

B. A. VANDERWERF, M.D., Ph.D.,
Medical Director.

Mr. MOORE. One last question, or actually two. Do all three of you agree with the necessity for the Federal Government to certify which physicians this country will allow to do transplants?

Dr. STARZL. They already do.

Mr. MOORE. The Federal Government certifies which physicians are allowed to do transplants?

Dr. STARZL. I believe that in a more direct pathway, they do.

Dr. SALVATIERRA. In the end stage renal disease program.

Mr. MOORE. You heard the testimony this morning from HHS that this is not the case.

Dr. SALVATIERRA. HHS is wrong or does not understand. For example, under those organ procurement programs, you do not qualify as an organ procurement program except if you satisfy certain standard criteria of eligibility [Federal Register 405.2101Q].

Mr. MOORE. We are going beyond that now in this bill.

Dr. SALVATIERRA. What you expect to do with this bill is to provide certain standard criteria for those centers that might be reimbursed. Certainly, and as part of the written testimony, what I have indicated, hopefully, we will have an advisory panel, similar to the panel on the task force, to provide the type of guidance in these areas. This is complex technology and not routine medical practice we are talking about.

Mr. MOORE. I am not sure that you have answered my question. I understand that for any organization, any hospital that receives medicare patients, it has to meet certain minimum standards, but we are going way beyond that now.

Now we are having the Federal Government say, Doctor, we are sorry, we have reviewed some of your patients, and we don't think you are qualified to do transplants anymore. The Federal Government says that you are no longer qualified to do transplants. That is what this bill calls for.

Dr. STARZL. What I said was, de facto that situation already is in place, and you have just heard how it is in place with the renal program. It is also in place with the cardiac and the liver programs.

For example, Dr. Brandt made an announcement this morning that children with biliary atresia and some other diagnoses—it was a thrilling moment for me, actually, to hear him say that people with certain diagnoses could be considered as covered by certain Federal agencies such as CHAMPUS. That was the thrill. But the depression follows when you reflect that all adults with liver disease are excluded, and this is a decision that has been made by the Government.

Mr. MOORE. It is the professional competency of the physician, that is what the bill calls upon HHS to now make for the first time.

Dr. STARZL. Let me give you another example, then. I know that in California, I just read about it, an act was passed by the California medicaid or medicare empowering Dr. Shumway, and only Dr. Shumway, to carry out cardiac transplantations in California.

Mr. MOORE. That is California's business. California as a state has traditionally licensed doctors, but the Federal Government hasn't.

Dr. STARZL. By Government, I mean the State as well as the Federal Government.

Mr. MOORE. One is very big. I am just wondering about that. I think that all three of you have danced around the question, and I can understand why. I don't think that any one of the three would really support this.

How do you determine now in your professional area who can be a member of your organization, you must have some standards for that. How do you determine now who can be a heart surgeon, who

can be an orthopedic surgeon, you don't come to the Federal Government for that. You have your own professional boards that do it. I am simply asking you why you need that here. It is a small part of the bill, but it is troubling.

Dr. SALVATIERRA. Mr. Moore, maybe I misread the bill, but I don't see where it is going to determine who is going to do that procedure. The Federal Government presently, for an institution to provide renal transplantation, definitely specifies as a requirement the facilities and the presence of a transplant surgeon [Federal Register 405.2102 7i and 7ii]. This has not interfered with the practice of transplantation, but has assured optimum results for the patient by having a qualified transplant surgeon perform the operation.

Mr. MOORE. But the bill goes beyond that. I will leave that question, I am obviously on thin ice with you.

Let me state one last point, and, Dr. Starzl, you commented on this. You were very disappointed in the delay that the Government has taken in declaring something not experimental but free to be used as a practice, as it was announced this morning that liver transplant in children is no longer experimental. You indicated that you were thrilled by that and for good reason.

How can you then suddenly trust the Federal Government now to make all these decisions that you have just criticized them for not making? How can you suddenly entrust them now to decide who is going to do transplants, on which patients and in which hospitals? Aren't they going to drag their feet there, too?

Dr. STARZL. I don't for a moment want to leave the impression that I trust the Government.

Mr. MOORE. But you have in this bill which you have endorsed.

Dr. STARZL. I think that the bill is a very open and thoughtful effort to rectify foot-dragging which has had its genesis within Government halls. I truly believe that. I think by creating a bureaucratic process in which decisions could be taken about what was service and what was experimental that it has become difficult, almost impossible, for some advanced forms of therapy, such as cardiopulmonary and hepatic transplantations, to develop.

Mr. MOORE. I understand your frustration.

Dr. STARZL. I think the bill, which I suppose is a reflection of the wishes of the people of all parties, is an attempt to rectify that situation, at least I see it that way.

When I first heard of this bill, I had many of the same concerns that you obviously have from the nature of your questioning this morning, as I am sure the people from Mr. Gore's office will attest. My first testimony was fundamentally faintly negative about this bill, but I have come to really believe in it. I think it is a good bill.

Mr. MOORE. I think that you are probably quite right in terms of what is experimental, I think the bill addresses that legislatively. But it also turns over to the Federal Government additional powers of certification. You have no assurance there that they won't drag their feet, and that is just a problem of dealing with the Federal Government.

Dr. STARZL. Yes, sir.

Mr. MOORE. If you are giving them power, you are giving yourself problems.

Dr. STARZL. I have tremendous trust in the legislative process, and perhaps more than in the bureaucratic process.

Mr. MOORE. But you see, in the bill we are turning over to the bureaucracy to do this certification procedure, which causes me fear, too. In any event, you have been satisfied, and I have yet to be satisfied.

Let me say this to all three of you. You are eminent surgeons. We have nothing but total respect for the work that you are doing and the great breakthroughs you are making. We would like nothing better than to do everything in the world we can to assist you. I just get a little chilled when the Federal Government comes to the assistance and starts regulating people. That is just a problem I have.

Dr. SALVATIERRA. Mr. Jacobs, can I make one small comment?

Chairman JACOBS. I bet you can.

Dr. SALVATIERRA. This is in reference to previous testimony. There seems to be considerable reliance on what the American Council on Transplantation may accomplish. Speaking from those who are involved in transplantation, we see that this organization will have essentially no effect on some of the critical urgent problems confronting transplantation presently.

It may help, certainly, in assisting with professional and public education. However, ACT, the American Council on Transplantation, is having considerable problems organizing themselves at present. I believe, in reference to the urgency of some of the problems facing transplantation, we do need other means.

Thank you.

Chairman JACOBS. Doctors, one quick question. Is cyclosporine overpriced?

Dr. SHUMWAY. I think it is, but remember this, the Sandoz Co. in Basle, Switzerland, that developed the drug provided it free of charge to many centers during a testing period when a lot of the statistics that I have given you were derived. So perhaps for the time being there is sort of a catchup period in their research and development.

Chairman JACOBS. I understand that it is not easy. If you sell a Rolls Royce, you ought to get what you can get for it. In other matters, it might be a little different.

Dr. STARZL. In trying to answer that question and put it in the context of this bill, I think the so-called amendment, the one that has to do with immunosuppression, should not just focus on one drug because that creates an Achilles' heel.

Chairman JACOBS. I am told that it does not specify just one drug.

Dr. STARZL. I think that if it just says "immunosuppressive drugs," it narrows it.

Chairman JACOBS. This one is apparently the top of the ladder at the moment.

Dr. SHUMWAY. At the moment.

Chairman JACOBS. We have to run. Thank you very much for your generous contribution to the record.

[Recess.]

Chairman JACOBS. Our next panel is from the American Medical Association represented by Dr. James E. Davis, vice speaker, accompanied by Dr. Fenninger, and Mr. Peterson.

Dr. Davis, welcome to the committee. You may proceed in your own manner.

STATEMENT OF JAMES E. DAVIS, M.D., VICE SPEAKER, HOUSE OF DELEGATES, AMERICAN MEDICAL ASSOCIATION, ACCOMPANIED BY LEONARD D. FENNINGER, M.D., VICE PRESIDENT, MEDICAL EDUCATION AND SCIENTIFIC POLICY; AND HARRY N. PETERSON, DIRECTOR, DIVISION OF LEGISLATIVE ACTIVITIES

Dr. DAVIS. Thank you, Mr. Chairman.

We are very pleased to be here, and we would like permission to submit a summary statement with the understanding that our entire statement will be incorporated in the minutes.

Chairman JACOBS. Without objection.

Dr. DAVIS. Mr. Chairman, my name is James E. Davis, M.D., I am a physician in the practice of general surgery in Durham, N.C. I am vice speaker of the American Medical Association's House of Delegates. Accompanying me are Leonard D. Fenninger, M.D., vice president for medical education and scientific policy for the AMA, and Harry N. Peterson, director of our Division of Legislative Activities.

As you know, sir, the organ procurement systems already in place in this country have made possible thousands of successful organ transplants. Thus, it is important as we look at the legislation before the committee that we recognize and preserve successful elements of the present procurement system. It is essential that any new Federal Government involvement should not create the risk that it may disrupt or restrict, rather than facilitate and expand, organ procurement and transplantation.

In our view, the National Organ Transplantation Act before you should not be adopted. Its provisions, indeed, have the strong potential for more harm than good, not only with respect to organ procurement and transplantation, but also with respect to delivery of medical care not involving organ transplantation. As a matter of fact, the greatest effects of this legislation could be felt in the provision of medical and health services other than organ transplantation.

As to the medicare and medicaid amendments, the bill would provide new, unprecedented authority to the Secretary of Health and Human Services under medicare. It authorizes the Secretary to determine whether technology or procedures furnished to medicare patients are reasonable and necessary by establishing medical criteria of general applicability regarding patient selection, regarding the qualifications for the person providing the technology or procedures, and regarding the facilities at which, as well as the conditions under which, such technology or procedures are provided.

Sir, let it be understood that this amendment is not limited—may I repeat, this amendment is not limited to transplant procedures or transplant technology, since the bill applies to all technology and procedures covered under medicare.

This authority granted to the Secretary by these amendments is alarmingly broad. It would authorize the Secretary to prescribe medical practice. It would authorize a cookbook approach to medical practice, with chapter and verse being written by the Secretary of Health and Human Services. Even if such a provision were to be limited to transplant procedures, such authority would constitute a highly improper intrusion into medical practice.

Mr. Chairman, we might be less concerned with this language if we thought that it was the result merely of drafting oversight. The Energy and Commerce Committee's report makes clear, however, that the committee intended the application well beyond transplantation.

When social decisions of the magnitude involved in this legislation are to be made, they should be addressed directly by the Congress, and not be shunted to a bureaucracy where priorities may not center on individual health needs but instead center on cost and expenditure controls. This provision should be rejected.

As to the ban on the purchase and sale of human organs, the American Medical Association agrees that the purchase or sale of human organs for transplantation should be banned. As was referred to this morning, our Judicial Council has developed an ethical opinion on this specific subject.

While we thus support the intent of the prohibition provision found in H.R. 4080, we nevertheless believe that the proposed language should not be adopted. We are concerned that under the language of the bill, a physician performing an organ removal or transplant involving a purchased organ may risk criminal prosecution and sanctions under other criminal statutes, even if the physician did not participate directly in the transaction of purchase or sale.

Mr. Chairman, in the time available today, I have discussed those portions of H.R. 4080 that are of greatest concern to us. Detailed comments on these provisions, as well as discussion regarding the provisions of the bill relating to organ procurement organizations, the U.S. Transplantation Network, and the HHS Task Force on Transplantation, are contained in our full statement, and I will not discuss them at this time.

In conclusion, sir, the American Medical Association is of the view that transplantation can be most beneficial to those who need it if the successful voluntary, private activities such as those currently ongoing in the private sector are left to work without the creation of a structure fashioned by the Federal Government. If nurtured in the private sector, transplantation, like other medical breakthroughs, will grow through research and experience to provide the greatest good to the greatest number of our patients.

The AMA finds objectionable the medicare amendments which could readily result in franchising of facilities and agency intrusion into the practice of medicine through cookbook regulatory criteria. As physicians, we are concerned with legislation that would prevent us from providing care based on our best medical judgment, instead of having to comply with a government list of eligibility and protocol.

As a practicing physician, wanting to provide the best treatment possible for my medicare patients, I would hope that I could contin-

ue to consult my medical textbooks instead of the Federal Register. It is that plain.

Certainly, the sale of organs should not be sanctioned. However, the language of H.R. 4080, creating the ban on transfers and imposing very severe penalties, could have far-reaching and unintended adverse results, and actually could inhibit the expansion of transplantation services.

We cannot support H.R. 4080, and we recommend against enactment of the legislation as it now stands. Mr. Chairman, we will be pleased to respond to any questions that you may have.

[The prepared statement follows:]

STATEMENT OF THE AMERICAN MEDICAL ASSOCIATION, PRESENTED BY JAMES E. DAVIS, M.D.

Mr. Chairman and Members of the Committee: My name is James E. Davis, M.D., and I am a physician in the practice of general surgery in Durham, North Carolina. I am Vice Speaker of the American Medical Association's House of Delegates. Accompanying me are Leonard D. Fenninger, M.D., Vice President for Medical Education and Scientific Policy for the AMA, and Harry N. Peterson, Director of our Division of Legislative Activities. The American Medical Association appreciates this opportunity to present testimony on H.R. 4080, the National Organ Transplantation Act.

The AMA commends this Committee for its interest concerning organ procurement and related transplantation matters and for bringing to public hearings the action of the committee on Energy and Commerce in reporting H.R. 4080. One of the primary purposes of the AMA is to improve the art and science of medicine. This commitment provides the background for our support for the development of new medical technology and procedures that prevent illness, and cure, treat or palliate the effect of illness or injury.

Mr. Chairman, as you know, the organ procurement systems already in place in this country have made possible thousands of successful organ transplants. Thus it is important as we look at the legislation before the Committee that we recognize and preserve successful elements of the present procurement system, even as we acknowledge that with additional resources greater benefits are possible. It is essential, however, that any new federal government involvement should not create the risk that it may disrupt or restrict, rather than facilitate and expand, organ procurement and transplantation. The risks are especially high in those areas where general questions of ethics, resource allocation, and the diffusion of new technology need further investigation.

In or view the National Organ Transplantation Act before you should not be adopted. Its provisions indeed have the strong potential for more harm than good, not only with respect to organ procurement and the systems operating today, but also with respect to delivery of medical care not involving organ transplantation. Moreover, Mr. Chairman, this bill would also in effect adversely modify drug availability and would in effect give new objectionable health planning authority to the Secretary of Health and Human Services. As a matter of fact, the greatest effects of this legislation could be felt in the provision of medical and other health services other than organ transplantation.

In general the bill provides for federal development of systems for acquisition and distribution of transplantable organs, for authority in the Secretary to limit availability of "technology and medical procedures" under Medicare and Medicaid and for a prohibition on the sale of organs. (A summary of principal provisions of the bill is attached.) Mr. Chairman, I will discuss each of these areas.

COMMENTS

Medicare and medicaid amendments

The bill would provide new, unprecedented authority to the Secreatry under Medicare. It authorizes the Secretary of HHS to determine whether technology or procedures furnished a Medicare patient are "reasonable and necessary" by establishing "medical criteria of general applicability" regarding:

- patient selection;
- the qualifications for the person providing the technology or procedure; and

the facilities at which, as well as the the conditions under which, such technology or procedures are provided.

Services to be provided and reimbursed under Medicare would thus be recognized at the broad discretion of the Secretary. We emphasize that this amendment is not even limited to transplant procedures or transplant technology as one might assume from the title of the bill. The language of the bill, to be added to general provisions of the Medicare law, applies to all technologies and procedures covered under Medicare. In pertinent part the bill provides as follows:

"The Secretary, after consultation with the Assistant Secretary of Health, may determine that a specific health care technology or procedure furnished with respect to a patient are 'reasonable and necessary' . . . only if the patient, the person furnishing the technology or procedure, and the conditions under which the technology or procedure are furnished meet such medical criteria of general applicability as the Secretary may specify."

The authority granted to the Secretary by these amendments is alarmingly broad and extremes in the regulatory process by the bureaucracy have been evident throughout the history of the Medicare program. There is no limit on the types of procedures or technology for which the Secretary could establish medical criteria. It would authorize the Secretary to prescribe conditions and standards controlling medical practice. It would authorize the "cookbook" approach to medical practice, with chapter and verse being written by the Secretary of HHS. Even if such a provision were to be limited to transplant procedures, the authority given the Secretary would constitute a highly improper intrusion into medical science and medical practice.

Mr. Chairman, we might be less concerned with this language if we thought it was the result merely of drafting oversight. The Energy and Commerce Committee's report makes clear, however, that the Committee intended the provisions to apply well beyond transplantation.

The Committee report describes broad powers under this authority, citing as appropriate examples its application even to "a new diagnostic imaging device, a new therapeutic agent, or a new type of surgery or surgical implant." The application of this power would thus broaden the authority of the Secretary to recognize procedures and services, and also create new restrictive authority over the availability of new technology, in effect giving new strength and impetus to the already discredited governmental activities under the federal health planning law. Is this intended, in fact, to be a health planning law? If, for example, the Secretary had this authority prior to the time of the CAT scanner debate, the existing widespread benefits of the CAT scanner might not be available today and its cost effective diagnostic benefits might have been denied to patients across the country. Under such authority, the fiscal pressures from OMB could result in denying Medicare patients—and in fact the patient population at large—the benefit of such a highly promising technology as the emerging nuclear magnetic resonance.

Moving a new technology from the experimental phase to a state of general availability does occur under existing mechanisms. A thorough consideration of the present system and appropriate modifications needs to take place instead of passing the whole matter on to the Secretary of HHS. When social decisions of the magnitude involved in this legislation are to be made, they should be addressed directly by the Congress and not be shunted to a bureaucracy where priorities may not center on individual medical and other health needs but instead center on cost and expenditure controls. This proposed grant of unprecedented authority to the Secretary is highly objectionable and should be rejected.

Organ procurement organizations

The bill provides for a four-year program of grants to plan, establish and initially operate Organ Procurement Organizations (OPOs). An OPO would work with health care facilities in its area to identify potential organ donors, acquire, type, preserve, allocate and transport donated organs. In addition, an OPO would participate in a U.S. Transplantation Network which the bill creates.

We believe that a system of local and regional organ procurement agencies can increase the number of organs available for transplant and should be encouraged. The AMA does not believe it is prudent, however, for the federal government to commit its resources to one procurement approach to the exclusion of all others, as the bill provides. Nor should it structure the local organizations. This would have the effect of prematurely fashioning and institutionalizing the system for the long term. Such a commitment should not be made without having the benefits of a comprehensive study. By only addressing exigencies of the moment, the federal govern-

ment risks repeating the long-term miscalculations which have become evident in some of our largest Federal health care programs.

U.S. transplantation network

The bill directs that up to \$2,000,000 a year be made available from the Medicare Part A trust fund to operate a "United States Transplantation Network." The function of the Network would be to facilitate organ transplants. The Network would establish a national registry of persons needing organs. Individuals would be matched with available organs through a computer system and a 24-hour telephone service.

We believe these provisions over-emphasize the mechanical aspects of organ procurement and matching. Moreover, private sector counterparts to the proposed hot-lines and computer systems do exist today. The success of these systems in matching organs, including several recently publicized cases, should be recognized. In addition, private sector network initiatives have the added benefit of not further depleting the Medicare Part A hospital insurance trust fund as would be the case under the network proposal of H.R. 4080. Since the Network is intended to aid many who are not Medicare beneficiaries, this choice of funding seems particularly inappropriate in light of concerns about the solvency of the Part A trust fund.

Task force

The bill directs the Secretary to establish a task force on organ transplantation. The function of the task force would be to "conduct comprehensive examinations of the medical, legal, ethical, economic and social issues presented by human organ procurement and transplantation." The task force would be composed of 19 members appointed by the Secretary. Within 6 months of its establishment the bill would have this task force conduct a national conference on organ transplantation to consider questions of access, allocation and payment.

The AMA strongly believes that the activities of such a task force should be a first step toward consideration of any long-term program to facilitate organ procurement and transplantation. Alternatives that are not included in this bill need to be considered. Moreover, the larger questions of resource allocation and of the access to new technologies need answers that may be applied to other situations in the future. One reservation with the task force provision of H.R. 4080 relates to its composition and its heavy emphasis on those professionals directly involved with current transplantations. We believe the task force would be better served if it more broadly represented the medical community. While the input of persons most familiar with the emerging technology of transplantation is crucial, those physicians who have already experienced the integration of a new medical technology in their field of practice could certainly add an important perspective as well.

Ban on purchase and sale of human organs

The bill would prohibit any person from buying or selling human organs. The bill would apply to kidneys, livers, hearts, lungs, pancreato, and any other human organ or tissues included by the Secretary of HHS in regulation. Heavy monetary fines and jail sentences are provided for violations. (This provision also provides that reasonable costs for the removal, storage and transportation of human organs would be allowed under Medicare.)

The AMA agrees that the purchase or sale of human organs for transplantation should be banned. The AMA Judicial Council, in interpreting the principles of medical ethics, has stated:

"The voluntary donation of organs in appropriate circumstances is commendable and is to be encouraged. However, it is not ethical to participate in a procedure to enable a donor to receive payment, other than for the reimbursement of expenses necessarily incurred in connection with removal, for any of the donor's nonrenewable organs."

Some states are now considering bills to prohibit the sale of organs. There is no evidence that encouraging the sale of organs would increase the number of transplants. To the contrary, encouraging the sale of organs would increase the cost of transplantation and undermine the voluntary organ donor procurement system. We believe the demand for organs can best be met through methods aimed at increasing voluntary organ donations from the pool of potentially available organs. While we thus support the intent of the prohibition found in H.R. 4080, we nevertheless believe that the proposed language should not be adopted. We are concerned that under the language of the bill a physician performing an organ removal or transplant involving a purchased organ may risk criminal prosecution and sanctions under other criminal statutes even if the physician did not participate directly in the transaction of purchase or sale. This could have the unintended result of inhibit-

ing the development of transplantation. In addition, we believe that blood and blood products should be explicitly excluded from the ban on the sale of organs and tissue. The maintenance of our nation's existing successful blood collection and distribution system should not be placed in jeopardy. Unintended disruptions must be avoided.

CONCLUSION

In conclusion, the AMA is of the view that the beneficial intent of this legislation can best be carried out by strengthening the many successful voluntary private activities currently ongoing, at both the local and regional levels, without the creation of a structure fashioned by the federal government. We believe that any national structure for organ procurement should be developed in the private sector, and that further study of the highly complex transplantation issues should be encouraged through an appropriate national commission or task force charged with the responsibility, after proper study, of making recommendations for needed modifications strengthening current private activities. The AMA finds particularly objectionable the Medicare amendments which could readily result in "franchising" of facilities and agency intrusion into the practice of medicine through "cookbook" regulatory criteria. While the sale of organs should not be sanctioned, the language in H.R. 4080 creating the ban on transfers and imposing very severe penalties could have far-reaching and unintended adverse results.

Because other avenues show more promise in addressing the problems of organ procurement and transplantation with much less risk, we cannot support H.R. 4080, and we recommend against enactment of the legislation as it now stands.

Mr. Chairman, we will be pleased to respond to any questions the Committee may have.

SUMMARY OF H.R. 4080, NATIONAL ORGAN TRANSPLANTATION ACT

ORGAN PROCUREMENT ORGANIZATIONS

The bill provides for grants to plan, establish and initially operate Organ Procurement Organizations (OPOs). An OPO would work with health care facilities in its area to identify potential organ donors, provide surgical quality standards, acquire, type, preserve, allocate and transport donated organs. An OPO must be structured as a non-profit entity. It must have an agreement with the Secretary of HHS to be reimbursed under Medicare for the procurement of kidneys and it must have procedures for obtaining payment for non-renal organs provided to transplant centers.

The service area of an OPO must be of sufficient size to include at least 50 potential organ donors a year and either include an entire metropolitan statistical area or be entirely outside such areas, or comprise an entire state. If the OPO is not a preexisting organ procurement entity, the bill requires it to have a board of directors representing hospital administrators, neurosurgeons or neurologists, intensive care or emergency room nurses, tissue banks, local voluntary health associations, the general public, and a practicing transplant surgeon from each transplant center in the service area. If the OPO is a preexisting organ procurement entity, the bill calls for it to establish an advisory board of similar makeup and function.

The bill prohibits funding of more than one OPO in a service area. In considering grant applications, the Secretary must give special consideration to existing organ procurement entities, and these funds could not be used for expenses covered by Medicare.

ADMINISTRATIVE UNIT

H.R. 4080 directs the Public Health Service (PHS) to establish and maintain an identifiable administrative unit for organ transplantation through 1987. This unit would administer organ procurement activities under the National Organ Transplantation Act and Medicare including the establishment of a United States Transplantation Network.

Also assigned to the PHS unit are the tasks of informing the public of the need for organ donations; providing technical assistance to relevant health care entities; and submitting to Congress an annual report on the status of organ donation and coordination of services, including an analysis of the effectiveness of procurement and allocation of organs and a description of any problems encountered in these activities.

TASK FORCE

The Secretary must establish a task force on organ transplantation. The function of the task force would be to "conduct comprehensive examinations of the medical, legal, ethical, economic and social issues presented by human organ procurement and transplantation." The task force would be composed of 19 members appointed by the Secretary:

At least six transplant surgeons and three more physicians in specialties related to organ transplantation;

Three non-physicians in the organ procurement field;

Four non-scientists from such fields as law, theology, ethics, health care financing or social science; and

Three members of the general public.

REGISTRY AND REPORT

In order to evaluate the scientific and clinical status of organ transplantation, the Secretary would be required to maintain a registry of recipients of organ transplants, including whatever information the Secretary deems necessary. Each year the Secretary would be required to issue a report on this subject, in consultation with the National Institutes of Health and the Food and Drug Administration. The annual report and other information related to the scientific and clinical status of organ transplantation would be made available to entities responsible for making payments for health care.

UNITED STATES TRANSPLANTATION NETWORK

The bill directs that up to \$2,000,000 a year be made available from the Medicare trust fund to operate a "United States Transplantation Network." The bill directs the Network to establish a national list of those needing organ transplants. These individuals would be matched with available organs through a computer system and a 24-hour telephone service. Samples of blood from those in need of a transplant would be distributed to transplant centers in their region to facilitate matching. Special emphasis would be placed on matching individuals whose immune system makes it difficult for them to receive organs. The Network would try to facilitate the distribution of any organ not used within the service area of the OPO which has acquired it. The Network would also coordinate delivery of organs. The Network would collect, analyze and publish data concerning organ transplants, establish standards of quality for the acquisition and transportation of organs and provide this information to physicians and other health professionals.

MEDICARE AND MEDICAID AMENDMENTS

H.R. 4080 would authorize the Secretary of HHS to determine whether a "specific health care technology or procedure" furnished a Medicare patient is "reasonable and necessary" by establishing "medical criteria of general applicability" regarding the patient, the person providing the technology or procedure, and the conditions under which such technology or procedures are provided. The Secretary could also designate specific centers for different procedures. Providers would be required to accept assignment. Reimbursement for immunosuppressive drugs furnished by a transplant center for up to 36 months after transplant surgery would be allowed under H.R. 4080. Reimbursement would be 80% of the reasonable amount as determined by the Secretary. Organ procurement activities would be exempt from Medicare prospective cost limits.

Absent a contrary state policy, the bill would also provide Medicaid coverage for organ transplants within designated medical criteria. Medicaid payment amounts for inpatient hospital services for transplants would reflect a Medicare DRG rate. Whatever information is required by the Secretary of HHS for the recipient registry would have to be provided by hospitals receiving payment for organ transplants through Medicare or Medicaid.

PURCHASES OF HUMAN ORGANS

Finally, H.R. 4080 would prohibit any person from buying or selling human organs, including kidneys, livers, hearts, lungs, pancreato, skin, bones, corneas or any other human organ or tissue included by the Secretary of HHS in regulation. Reasonable costs for the removal, storage and transportation of human organs would be allowed.

Chairman JACOBS. Thank you, Dr. Davis.

I suppose the record should show that we have had two panels of medical doctors in tandem, and we are now having what you could call a second opinion, I suppose, on the legislation.

On the ban of the sale of organs, perhaps you were present when the administration witnesses testified that the objection of the administration was that it should be done at the State level rather than the Federal level. As I understand it, you object to it no matter what level it is done on.

Dr. DAVIS. Exactly.

Mr. PETERSON. Mr. Chairman, we are saying that it is appropriate to have a ban, but what we are suggesting here is that this language that is in the bill would go so far as affecting a physician involved in the transplantation, even though he was not involved in the unlawful sale or transfer. There are other statutes that might be interpreted as implicating the physician as aiding and abetting.

Chairman JACOBS. So if there was exculpatory language for the physician, you would have no objection.

Dr. DAVIS. I thought you were referring to the moral obligation.

Chairman JACOBS. It is like the exclusionary rule in a criminal trial. You catch this fellow redhanded with \$10 million worth of heroin. You know that he is guilty but it is not admissible because someone didn't tap dance or genuflect in obtaining the evidence.

Mr. PETERSON. If the exclusionary rule were fashioned to say that even though he knew that—

Chairman JACOBS. I appreciate that. If you are standing over a person who is about to die, and someone says, here is a good liver, and that person will have to die because somebody sold it, later would be the time to take care of that.

I agree with you that there ought to be exculpatory language, so long as it cannot be established that the physician was in business with the people who did the selling. I think that that is perfectly reasonable.

Do you have any objection, as the administration does, and I understand did not last night, on the Federal prohibition against the sale of organs as distinguished from individual States, or leaving it to the States?

Dr. DAVIS. No, we would not. We oppose it in any form.

Chairman JACOBS. I appreciate that, but with the caveat that I have just accepted, for the sake of discussion, you would have no objection to the Federal Government as distinguished from the State governments carrying out that particular feature, would you?

Dr. DAVIS. No, sir.

Chairman JACOBS. We are out of time again, I am terribly sorry. The bells keep ringing. We will recess for a moment and come back.

[Recess]

Chairman JACOBS. We will reconvene.

Our next panel is the American Liver Foundation, Gail Rempell, member, board of directors, and the National Kidney Foundation, Dr. David A. Ogden, president.

Mrs. Rempell, you should proceed first, since you are listed first.

STATEMENT OF GAIL REMPELL, MEMBER, BOARD OF
DIRECTORS, AMERICAN LIVER FOUNDATION

Mrs. REMPELL. Thank you, Mr. Chairman.

I am Gail Rempell. I am here because I refuse to let my daughter die. My 6-year old daughter, Pamela, has advanced cirrhosis of the liver caused by biliary atresia. At any moment, she could have a life threatening hemorrhage at home or as she sits in school with other healthy 6-year olds.

Her skin is greenish yellow in color and she itches from head to toe, day and night. She is living and we are living on the edge of disaster every minute. Her dad and I live in the hope and fear of the day when she will have to have a liver transplant, or she will die.

Members of the panel, we must move ahead as rapidly as possible to support the expansion and improvement of an efficient national system of organ procurement and distribution. I am told that 25 percent of the children waiting for liver donors die before a liver can be found.

Physicians and surgeons are recommending transplants for critically ill patients, children as well as adults. However, today, decisions are being made by hospital administrators or accounting departments as to who will live and who will die according to their ability to pay the bill.

What happened to equal opportunity when the rich can live and the poor must die? We must respond to a critical human need and provide financial assistance to those patients, children as well as adults, who need it.

Another major concern we have is; how can we as lay people be assured of the quality of care in transplant centers. We need this legislation to analyze and evaluate, and give us confidence that our loved ones will get the best possible treatment. We need your help!

As you know, we have only scratched the surface in educating the public about the need for organ donors. Health professionals are first on the list of those who need to be informed. The American Liver Foundation, on whose board I serve, is mounting a major effort in this area.

The medicare coverage for the immunosuppressive drugs required to maintain the life of the transplant patient is not adequate as described in the legislation. These patients will die if they don't continue to receive this medication for the rest of their life. Can we afford to make an investment of \$100,000 to \$200,000 to do a transplant and let the patient die for lack of these life supporting drugs?

We applaud the work of the American Council on Transplantation. They have identified the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation, and are attacking these problems head on.

The establishment of a task force at this point would seem to us to be a duplication of their efforts. We know what the problems are. We need solutions. Dollars spent to establish a task force now could be better spent solving some of the critical problems.

The remarkable advances made possible through research have given us the hope for life beyond tomorrow for our precious loved

ones. We can't afford to waste a single minute of indecision about what needs to be done.

We have been listening for months to the pleas for organ donors and to the begging for nickles, dimes, and dollars to pay for transplants by desperate families.

There is an urgency to my plea, Mr. Chairman. Pamela and hundreds of others like her will die if we don't act today and forge ahead.

As a representative of thousands of victims of liver disease who are members of the American Liver Foundation, I implore you to act now.

Mr. Chairman, I would like to call your attention to the donor dove pin which I am wearing on my lapel, designed by the American Liver Foundation, which is meant to symbolize one's commitment to the donor awareness program. We sincerely hope that it will be adopted nationwide by others who share this commitment.

I would like to thank you in advance, Mr. Chairman, for wearing the donor dove pin, which you will find attached to my statement. [The prepared statement follows:]

STATEMENT OF GAIL REMPELL, MEMBER OF BOARD OF DIRECTORS, AMERICAN LIVER FOUNDATION

I am Gail Rempell—I am here because I refuse to let my daughter die. My six year old daughter Pamela, has advanced cirrhosis of the liver caused by biliary atresia. At any moment she could have a life threatening hemorrhage at home or as she sits in school with other healthy six year olds.

Her skin is a greenish yellow color and she itches from head to toe, night and day. She is living on the edge of disaster every minute.

Her dad and I live in constant fear of the day when she will have to have a liver transplant—or she will die.

Members of the panel, we must move ahead as rapidly as possible to support the expansion and improvement of an efficient national system of organ procurement and distribution. I am told that 25% of the children waiting for liver donors die before a liver can be found.

Physicians and surgeons are recommending transplants for critically ill patients. However, today, decisions are being made by hospital administrators, or accounting departments as to who will live and who will die, according to their ability to pay the bill. What happened to equal opportunity, when the rich can live and the poor must die? We must respond to a critical human need and provide financial assistance to those patients, children as well as adults, who need it.

Another major concern we have is: How can we as lay people be assured of the quality of care in transplant centers? We need this legislation to analyze and evaluate and give us confidence that our loved ones will get the best possible treatment. We need your help!

As you know, we have only scratched the surface in educating the public about the need for organ donors. Health professionals are first on the list of those who need to be informed. The American Liver Foundation, on whose Board I serve, is mounting a major effort in this area.

The medicare coverage for the immunosuppressant drugs required to maintain the life of the transplant patient is not adequate as described in the legislation. These patients will die if they don't continue to receive this medication for the rest of their lives. Can we afford to make an investment of \$100-200,000 to do a transplant and let the patient die for lack of these life supporting drugs?

We applaud the work of the American Council on Transplantation. They have identified the medical, legal, ethical, economic and social issues presented by human organ procurement and transplantation and are attacking these problems head on. The establishment of a task force at this point would seem to us to be a duplication of their efforts. We know what the problems are. We need solutions! Dollars spent to establish a task force now could be better spent solving some of the critical problems.

The remarkable advances made possible through research have given us hope for life beyond tomorrow for our precious loved ones. We can't afford to waste a single minute of indecision about what needs to be done.

We have been listening for months to the pleas for organ donors and to the begging for nickels, dimes and dollars to pay for transplants by desperate families.

There is an urgency to my plea. Pamela and hundreds of others like her will die if we don't act today and forge ahead.

As a representative of thousands of victims of liver diseases who are members of the American Liver Foundation, I implore you to ACT now.



Transplants A gift of life

Questions and Answers About the Organ Donor Program

Donated organs save lives.

Organ donation is an important decision. And it is one that should be considered carefully.

Yet for thousands of people there is no decision to make. They are waiting for a transplant . . . waiting for enough people to donate their organs leaving them a legacy of renewed life. Many wait in vain.

The human body is a storehouse of valuable tissue and organs. However, we still lack enough organs from children as well as adults for those who are in need of transplants.

BECOME A DONOR. Give new life to someone.

How successful are organ and tissue transplants?

Transplantation of organs from one person to another was first attempted in the 19th century. However, it was not until the 1960's that significant progress was made in solving the problems of tissue preservation, surgical technique and rejection.

Today, kidney, liver and heart transplantations are well accepted therapies which are performed routinely at specialized transplant centers saving thousands of lives each year. In the United States, the number of kidneys transplanted each year is approximately 4,000. There will be approximately 100 hearts and 100 livers transplanted this year. The longest surviving recipients of both liver and heart transplantation are over 13 years post transplant.

Heart transplants now have almost 70% one year survival and approximately 50% five year survival. Corneas have approximately 90% graft survival at one year. Liver transplants have about a 60% one year survival rate.



Gift of Life Organ Donor Program

Sponsored by
AMERICAN LIVER FOUNDATION

998 Pompton Avenue Cedar Grove, N.J. 07009
(201) 857-2626 OR (412) DONORS 7



Questions and Answers About the Organ Donor Program

Why do we need more donors?

The success of transplantation is influenced by the quality and quantity of organs and tissues available. Liver and kidney recipients rely mostly on attending physicians and staff and concerned individuals to recognize suitable patients as donors. It is they who usually discuss with families the opportunity to donate the organs of their loved one. Carriers of Uniform Donor Cards confirm their willingness to be an organ donor.

How many people are waiting for liver transplants?

There are over 100 adults as well as children waiting for liver transplants and the number is growing annually. It would greatly facilitate the recovery of organs for transplantation if more people signed and carried Donor Cards.

If I move to a different state, do I have to fill out another card?

No, this card is legal in 50 states.

Is there any possible conflict between saving my life and using my organs for transplant?

No. By law, determination of death is the responsibility of licensed physicians. They are required to sustain life until death has been determined with absolute certainty. The law in every state prohibits a physician who is caring for a patient from being involved in the donation and transplantation of that patient's organs after death.

What can I donate?

The Uniform Donor Card enables you to donate:

- All organs
- Specific organs
- Your entire body for medical research.

Note: You can donate your entire body and/or any organs. Check with the nearest teaching hospital for details on donation of your entire body.

Can anyone sign a Donor Card?

Donor Cards are only legal documents if the donor is 18 or over. To insure that your wishes are respected, always keep the cards with you. They are legal documents.

Minors under the age of 18 may complete Donor Cards but they will not be considered as legal documents even if the signature is witnessed by a parent or legal guardian. The donation of organs of minors may be made at the time of death only by the parent(s) or legal guardian.

This should be an important consideration for parents/legal guardians or minors since there is an equal demand for pediatric as well as adult organs.

Is there a donor registry?

There is no national organ donor registry; since such a registry would be logistically and economically impractical.

What about my will?

The Donor Card is an instant will. A provision in your will may not be discovered until it is too late. Organs and tissues must be recovered immediately after death.

Can I change my mind?

Yes, simply tear up your records. New ones can be obtained at a later date if you wish.

Will my estate be paid or have to pay for organ donation?

No costs are incurred by the organ donor or his heirs. No payment may be made to the donor or the heirs.

What about funeral costs or burial arrangements?

Removal of organs or tissues authorized by a donor will not interfere with customary funeral or burial services. Furthermore, this procedure is carried out as a regular surgical procedure and will not in any way disfigure the body. Regular funeral costs, memorial services or burial arrangements remain the responsibility of relatives or persons in charge of the estate.

What about religion and transplantation?

Authorities of all major religions have indicated that signing and carrying the Donor Card is sanctioned by the life-saving traditions of each respective religion. If you have any questions about the religious acceptability of organ donation, consultation with clergy of your faith is advised.

What happens when organs are donated?

Organ and tissue retrieval is accomplished by regional organ banks. Contacting the nearest organ bank may be accomplished through your local hospital.

Special surgical teams are mobilized. The Regional Transplant Program tissue typing labs are notified to begin cross-matching and a search is made for the best possible recipient. The liver and other organs are retrieved as soon as possible, packed in ice and transported by auto, air, military transport or police helicopters to reach their destination as quickly as possible.

The Uniform Anatomical Gift Act has been passed in all fifty States. This makes it possible for anyone to legally donate his organs upon death by filling out the Uniform Donor Card. Sign it in the presence of two witnesses and carry it with you at all times. Inform your family so that your wishes will be carried out.

If you have any more questions or need more cards for your family or friends, call or write:

AMERICAN LIVER FOUNDATION

698 Pompton Avenue
Cedar Grove, N.J. 07009
(201) 857-2626



In hope that I may help others, I hereby make this anatomical gift, to take effect upon my death. The words and marks below indicate my desires.
I give: _____ Any needed organs or parts.
or: _____ Only the following organs or parts:

For the purposes of transplantation, therapy, medical research or education.
Signed by the Donor and the following two witnesses in the presence of each other.

Signature of Donor _____ Date of Birth of Donor _____
Date Signed _____ City & State _____
Witness _____ Witness _____
This is a Legal Document Under the Uniform Anatomical Gift Act.

Chairman JACOBS. Thank you, Mrs. Rempell.
Dr. Ogden.

**STATEMENT OF DAVID A. OGDEN, M.D., PRESIDENT, NATIONAL
KIDNEY FOUNDATION**

Dr. OGDEN. Mr. Jacobs, committee members, ladies and gentlemen.

I am Dr. David Ogden, president of the National Kidney Foundation, and professor of medicine, and chief of the renal section of the University of Arizona College of Medicine.

Perhaps I should say who I am not. I am not a transplant surgeon nor do I represent a physician group. But I speak to this committee on behalf of the many thousands of nonprofessional and multidisciplinary professional volunteer members of the National Kidney Foundation, the leading voluntary health organization dedicated to the needs of people with kidney and urologic disease.

In the interest of time, and since we have previously testified concerning other aspects of H.R. 4080, I shall restrict my formal comments to title II, the medicare and medicaid amendments.

With respect to immunosuppressive drugs, the National Kidney Foundation recommends immediate amendment to title XVIII of the Social Security Act to provide for medicare part B payments for immunosuppressive drugs, if the drug is approved by the Food and Drug Administration, used in connection with a transplant for which payment can be made under medicare, and furnished to the beneficiary by a transplant center within 3 years after the transplant was performed.

This amendment would apply to presently available immunosuppressive drugs, particularly azathioprine, steroids, cyclophosphamide, and cyclosporine, and future immunosuppressants as developed and approved by the FDA.

There is little question that cyclosporine and its considerable cost for both purchase and safe use, has prompted consideration of a specific amendment of title XVIII to provide for its payments and its use. Without medicare payment for cyclosporine, and most likely for future immunosuppressants, such drugs will be effectively unavailable to most transplant candidates.

If these drugs are not made financially feasible this will prejudice against transplantation, particularly in the cases of the previously unsuccessful transplanted patient, the sensitized patient, the older patient, and perhaps cadaveric renal transplant candidates in general.

In the absence of medicare payment for new immunosuppressants, the vast majority of patients will be denied the technological advance such drugs represent. The means of preventing graft rejection will be an economic, not a medical decision. Economic reality is, of course, playing an increasing role in medical decisionmaking, and will undoubtedly influence availability of new technologies and perhaps the quality of medical care available to our people in the future.

Patients with end stage renal disease are entitled to medicare benefits for either chronic dialysis or transplantation. The question here, economically, concerns the relative cost of chronic dialysis

versus the cost of transplantation with cyclosporine and steroids, or with conventional immunosuppressants.

There are legitimate differences of scientific opinion concerning the relative effectiveness of cyclosporine as opposed to conventional immunosuppressive therapy. Evidence suggests that cyclosporine together with steroid treatment is the treatment of choice for cadaveric renal transplants and perhaps for living donor renal transplants. It is certainly the treatment of choice for nonrenal whole organ transplants.

Cyclosporine has a number of undesirable side effects, including kidney and liver toxicity, abnormal hair growth, overgrowth of gums, mental depression, and others. The most worrisome of these is its kidney toxicity which may limit its long-term use in both cadaver and related-donor kidney transplants. We hope equally or more efficacious drugs with fewer side effects will be developed and become available in the future.

We don't know yet how best to use cyclosporine in renal transplantation. Which patients benefit most? How much of what drugs to use with it? How often should we measure its blood level? But we are learning more and more about all these aspects of its use.

Since there is not unanimity of thought concerning cyclosporine in comparison to conventional immunosuppressants, no one can accurately predict its cost or savings to the end stage renal disease program. Any such analysis must include effects of the drug on the number of transplants performed, the types of transplants performed, the number of patients remaining on dialysis, and the patient and graft survival rates, including the number of patients returning to dialysis after an unsuccessful graft.

Some of these effects may take several years to become apparent, and may be clouded by other changes in renal transplantation, especially any increase in cadaver organ availability prompted by recently enhanced public interest and/or Government initiatives in this area. Thus, we may never be able to accurately assess the cost or savings directly due to use of cyclosporine or future immunosuppressant drugs.

There is little doubt that the cost of transplants will increase with cyclosporine as compared to conventional immunosuppressant drugs. Our analysis, however, based on a number of necessary assumption, indicates that the ESRD program net cost will be relatively decreased. That is, rising program costs will increase at a reduced rate with the use of cyclosporine as compared to its increase without the use of cyclosporine. ESRD program costs per beneficiary will decrease since the rate of growth of chronic dialysis patients will be decreased by transplantation with cyclosporine.

In summary, cyclosporine can be expected to provide an overall, significant, improvement in graft and patient survival in renal and nonrenal whole organ transplantation. Without medicare payment, this and future immunosuppressants will not be available to the vast majority of transplant candidates.

For these reasons alone, title XVIII of the Social Security Act should be amended as suggested. The cost or savings to the end stage renal disease program cannot be accurately assessed at this time.

I would like to make a short statement concerning reimbursement for nonrenal organ transplantation.

The National Kidney Foundation has a legitimate interest in nonrenal organ transplantation because of its nearly 20-year effort in public and professional education, facilitation, and research in organ donation, procurement, and preservation.

We support the concept of reimbursement for nonrenal organ transplantation in centers designated and approved for such transplantation by the Secretary of Health and Human Services. We feel that specific criteria for approval and designation of such centers are beyond the expertise available within the foundation. We would like to suggest, however, that only hospitals approved for kidney transplantation be considered for designation for nonrenal organ transplantation. This would provide effective resource management, and would avoid wastage of transplantable organs.

Thank you for your attention.

[The prepared statement follows:]

STATEMENT OF DAVID A. OGDEN, M.D., PRESIDENT, NATIONAL KIDNEY FOUNDATION

Mr. Chairman, Committee Members, ladies and gentlemen: My name is David A. Ogden, M.D., President of National Kidney Foundation, and Professor of Medicine and Chief of the Renal Section of the University of Arizona College of Medicine. I appreciate the opportunity to speak to this committee on behalf of the many thousands of non-professional and multidisciplinary professional volunteer members of the National Kidney Foundation, the leading voluntary health organization dedicated to the needs of people with kidney and urologic disease.

I will restrict my formal comments to Title II—Medicare and Medicaid Amendments.

IMMUNOSUPPRESSIVE DRUGS

The National Kidney Foundation recommends immediate amendments to Title XVIII of the Social Security Act to provide Medicare Part B payments for immunosuppressive drugs, if the drug is: (1) approved by the Food and Drug Administration; (2) used in connection with a transplant for which payment can be made under Medicare; and (3) furnished to the beneficiary by a transplant center and furnished within 3 years after the transplant was performed.

This amendment, if adopted, would apply to presently available immunosuppressive drugs (azathioprine, steroids, cyclophosphamide, cyclosporine) and future immunosuppressants as developed and approved by the FDA. There is little question, however, that cyclosporine and its considerable cost for both purchase and safe use, has prompted consideration of a specific amendment of Title XVIII to provide for its payment and, therefore, its use. Without Medicare payment for cyclosporine, and most likely for future immunosuppressants, such drugs will be effectively unavailable to most transplant candidates. If these drugs are not financially feasible to use, this will prejudice against transplantation, particularly of the previously unsuccessfully transplanted patient, the sensitized patient, the older patient, and perhaps cadaveric renal transplant candidates in general.

In the absence of Medicare payment for new immunosuppressants, the vast majority of patients will be denied the technological advance such drugs represent. The means of preventing graft rejection will be an economic, not a medical, decision. Economic reality is, of course, playing an increasing role in medical decision-making, and will undoubtedly influence availability of new technologies and perhaps the quality of medical care available to our people in the future. In this instance, however, patients with end-stage renal disease are entitled to Medicare benefits for either chronic dialysis or transplantation. It thus becomes a question, economically, of the relative cost of chronic dialysis as opposed to transplantation with cyclosporine and steroids, or with conventional immunosuppressants.

There is legitimate difference of scientific opinion concerning the relative effectiveness of cyclosporine vs. conventional immunosuppressive therapy. The balance of evidence suggests that cyclosporine together with steroid treatment is the treatment of choice for cadaveric renal transplants and perhaps for living donor renal transplants. It is certainly the treatment of choice for previously sensitized trans-

plant candidates. It is certainly the treatment of choice for non-renal whole organ transplants. It has a number of undesirable side effects, including kidney and liver toxicity, hirsutism (abnormal hair growth), gingival hypertrophy (overgrowth of gums), mental depression, and oothers. The most worrisome of these is its kidney toxicity, which may well limit its long-term use in both cadaver and related-donor kidney transplants. We hope equally or more efficacious drugs with fewer side effects will be developed and become available in the future.

We do not yet know how best to use cyclosporine in renal transplantation—which patients benefit most—how long to use it—how much of what drugs to use with it—how often to measure its blood levels; but there is increasing knowledge concerning all these aspects of its use. Since there is not unanimity of thought concerning its use, and since there is no definitive cost-benefit analysis of its use in comparison to conventional immunosuppressants, it is impossible to accurately predict its cost—or savings—to the End-Stage Renal Disease Program. Any such analysis must, of course, include effects of the drug on the numbers of transplants performed, the types of transplants performed, the number of patients remaining on dialysis, and the patient and graft survival rates including the impact of patients returning to dialysis after an unsuccessful graft. Some of these effects may take several years to become apparent, and may be clouded by other changes in renal transplantation, especially any increase in cadaver organ availability prompted by recently enhanced public interest and/or government initiatives in this area. Thus, we may never be able to accurately assess the cost—or savings to be achieved with cyclosporine or future immunosuppressant drugs.

I have prepared the following table which suggests the relative changes in costs to be expected per transplant with and without cyclosporine based on experience to date. Our own cost analysis, based on many necessary assumptions, suggests a very considerable ESRD program net cost savings will result from the use of cyclosporine in renal transportation.

CADAVER RENAL TRANSPLANTATION—PER TRANSPLANT COST ANALYSIS

	With cyclosporine	Without cyclosporine
Transplant hospitalization.....	Decreased.	Same.
Subsequent hospitalization.....	Decreased.	Same.
First year.....		
Second year.....		
Third year.....		
Out-patient visits.....	Increased or same.	Same.
Donor organ.....	Same.	Same.
Cyclosporine.....	Increased.	—
Cyclosporine blood serum assays.....	Increased.	—
Other immunosuppressants (azathioprine, steroids, ALG).....	Decreased.	Same.
Differentiation of decrease in function ¹	Increased.	Same.

¹ Rejection versus obstruction versus cyclosporine nephrotoxicity, that is, renal biopsy, sonogram, IVP, radionuclide studies.

In summary, cyclosporine can be expected to provide an overall, significant, improvement in graft and patient survival in renal and non-renal whole organ transplantation. Without Medicare payment, this and future immunosuppressants will not be available to the vast majority of transplant candidates. For these reasons alone, Title XVIII of the Social Security Act should be amended as suggested. The cost—or savings—to the End Stage Renal Disease Program cannot be accurately assessed at this time.

REIMBURSEMENT FOR NON-RENAL ORGAN TRANSPLANTATION

The National Kidney Foundation has a legitimate interest in non-renal organ transplantation because of its nearly 20 year effort in public and professional education, facilitation, and research in organ donation, procurement, and preservation.

We support the concept of reimbursement for non-renal organ transplantation in centers designated and approved for such transplantation by the Secretary of Health and Human Services. We feel that specific criteria for approval and designation of such centers are beyond the expertise available within the Foundation. We would like to suggest, however, that only hospitals approved for kidney transplantation be considered for designation for non-renal organ transplantation. This would

provide effective resource management, and would avoid wastage of transplantable organs.

Thank you for your attention.

Chairman JACOBS. Mrs. Rempell's testimony is partially a fulfillment of statement made by the administration earlier today. Were you here when the administration said that undoubtedly they would be pleased to have Government payment of the drug past the 36-month period, we just heard that plea. Why is the legislation limited to 36 months in the first place?

Dr. OGDEN. There is no medical rationale for that. In fact, in the case of a patient doing well at 36 months with a kidney or other organ transplant, who might then, because of financial reasons, be deprived of further medication, such a limitation would obviously be a catastrophe. If that patient had to switch to conventional immunosuppression, I think we could expect a certain loss of organs and life at that time.

Chairman JACOBS. Then, I take it, it would be reasonable to accept the administration's caveat as a serious one concerning the expectation of the time period in which payment might be made by the Government.

Dr. OGDEN. The reason it was limited is that under current regulation and medicare law, reimbursement for any aspect of transplant care is limited to 36 months following the transplant. This was simply in conformity with present law.

You are right, it makes neither medical sense, nor economic sense, to force this kind of conversion in 3 years. Ideally, the law should be modified to allow continued therapy.

Chairman JACOBS. Dr. Ogden, I don't mean to quibble, but the chief sponsor of this legislation stated this morning that the Congressional Budget Office had inferred that the matter would be revenue neutral. You, on the other hand, have indicated that it actually would represent a savings to the Government. Can you account for that disparity?

Dr. OGDEN. Varying estimates reflect the number of expense factors each group has considered. We have taken the approach of what it costs to dialyze a patient for a year. That is only a part of the costs. The program costs include the cost of hospitalizing that patient an average of 27 days a year in the hospital, and physician fees which are not included in the allowable charge for dialysis. In other words, we are looking at an incomplete picture when we make a superficial analysis.

What we really need is to know what it cost the ESRD program to maintain a dialysis patient—professional fees, hospital costs, new blood access costs, and dialysis costs for 3 years—and how that compares with the cost of a transplant and followup care for 3 years. Then we would have to add the cost of cyclosporine or immunosuppressant to the transplant cost.

Even then, even looking at the historical data, which I have never heard presented and have never seen in print either, then we still wouldn't have comparative cost figures because the impact of cyclosporine on the number of people who are and could be transplanted would have to be learned. We need to find that out.

Chairman JACOBS. Mrs. Rempell, your testimony is very eloquent and very touching, and I shall do the best I can to convey the demeanor of it to members who are not able to be present.

Mrs. REMPELL. Mr. Chairman, may I say something?

Chairman JACOBS. Sure.

Mrs. REMPELL. When Pamela was born, her surgeon, Dr. Keith Schneider, said that in children we are shooting for the whole ball of wax. To buy a child a year or two, when the child is a week or two old, it is really not what we wanted, we wanted to buy her a lifetime. I think that that is how we would go into a transplant at this point.

If we were to go through this transplant only to know that within 3 years this drug would be cut off, and we could not find the funding for it, I don't know how many of us would put our children through that or go through it ourselves.

Chairman JACOBS. We have some interesting issues in the Congress for the American people generally about the priorities, how this Government spends the taxpayers money, borrows against tax money sometime in the future, drives up interest rates, and so on.

I hope that it is not inappropriate to observe that the price tag at the moment for whatever we are doing in Lebanon is approximately \$125 million. I hope that it is not too harsh to point out that there has been a lot of transplantation of hard substances into our fellow citizens there who are no longer living.

So we have some basic questions of priorities, and we are only supposed to discuss those things upstairs in the Armed Services Committee hearings, and we are only supposed to discuss these things downstairs at this committee. But it seems to me that in any reasonable mind, it is the same Government, and it is the same money, and we ought to be mindful, it seems to me, of how our priorities are arrived at in this country.

I think it was Mr. Friendly who wrote a book called "Due to Circumstances Beyond Our Control," and the preface, or something toward the front of the book, said: "What you don't know can kill you, and what you don't know can rip you off." I don't think that it is altogether inappropriate for people to consider these matters.

The administration is opposed to this legislation, and that viewpoint, I am sure, will be given careful consideration by this subcommittee. The ranking minority member of the subcommittee has indicated some serious question about the legislation as well.

It does seem that the entire budget ought to be taken into consideration insofar as budgetary questions are raised in this legislation. I note that the administration is asking the Congress to embark on a new \$8 billion space program.

All of those things, it seems to me, ought to be taken into account. When you go around the country and give talks, you might take that into account.

Thank you very much.

The next panel consists of the American Association of Tissue Banks, represented by Mr. Robert E. Stevenson; the Eye Bank Association, represented by Mr. Snyder; the University of Texas Health Science Center at Dallas, represented by Ellen Heck; finally, The Living Bank International, Mrs. Glen W. Karsten.

Dr. Stevenson, would you proceed in your own manner.

**STATEMENT OF ROBERT E. STEVENSON, PH.D., CHAIRMAN,
STANDARDS COMMITTEE, AMERICAN ASSOCIATION OF TISSUE
BANKS**

Mr. STEVENSON. Thank you, Mr. Chairman, for this opportunity to comment on the National Organ Transplant Act, H.R. 4080. I am Robert Stevenson. I have had 25 years of experience in working with human tissue programs, and I am appearing today on behalf of the American Association of Tissue Banks to present its views. I am chairman of the AATB Standards Committee.

I have written comments, but I would prefer to focus on a few points, if you don't mind.

Chairman JACOBS. Without objection, they will be included in the record.

Mr. STEVENSON. Thank you.

While the humanitarian intent of this proposed legislation is beyond question, we feel that focusing primarily on the retrieval of organs will stultify medical progress by failing to encourage also the retrieval of multiple tissues. As written, it will encourage fragmentation of community support and donor recruitment, institutionalize competition for limited donor resources, and duplicate many administrative and logistics costs in organ and tissue procurement.

[The prepared statement follows:]

**STATEMENT OF ROBERT E. STEVENSON, PH.D., AMERICAN ASSOCIATION OF TISSUE
BANKS**

This bill is a praiseworthy attempt to further the nation's ability to provide life saving medical therapy and to organize improved voluntary donation of human organs for that purpose.

Focusing as it does however, upon solid organ transplants, it tends to ignore the usefulness of other tissues and will, if enacted as written, make an already difficult situation worse in respect to those materials.

In the past 30 years medical science has learned that a variety of human tissues are valuable in reparative procedures and, despite progress in materials science, has found that plastics and synthetics are still inferior to what nature provides.

Unlike kidneys, hearts or livers, these tissues do not have to be viable or freshly obtained. The most commonly used tissues include cornea, bone, skin, dura (the covering of the brain), fascia (a connective tissue), artery, vein, heart valves, nerve, glandular tissues, bones of the inner ear and the eardrum. With the exception of corneas, these tissues can be collected up to 23 hours after death. Corneas must be obtained within 6-8 hours. Many of these tissues may be preserved by freezing or freeze-drying techniques and stockpiled against future need.

To give some idea of the unfilled need for skin as a biological dressing for third degree burns, Col. Basil Pruitt, Head of the Army's Burn Research Unit at Ft. Sam Houston, estimates that 10,000 patients per year in the U.S. would materially benefit from treatment with human allograft skin. To supply this amount of skin, 5,000 cadaver donors would be required. We are currently realizing only a fraction of this goal. Stockpiling for disasters such as the burned Marines from Lebanon has not been possible and never will be until a larger number of combined procurement and banking facilities are established.

To cite another example, it is estimated that nearly 500,000 bone transplant are conducted annually in the nation. Almost all of these are transplants of bone from some other location in the patient. This requires a second operative procedure with its accompanying risks and a limitation on the amount and type of bone that can be obtained. Virtually all of these transplants could be made with bone from cadaver donors. Certain transplants, such as the replacement of joints or sections of long bones removed because of tumors or trauma, can only be achieved using cadaver transplants. Bone can be stored frozen or freeze-dried and is prepared in a variety of forms such as bone sections, chips, slabs, ground or powdered bone. Powdered bone is used by the dental profession for filling defects in the jaw.

Most existing organ procurement organizations primarily serve the needs of kidney transplantation. There are technical and financial reasons for this. The ideal kidney donor is brain dead and being maintained on life support systems in hospital intensive care units. Timely retrieval after death is critical. Surgical teams and operating room charges are heavy and the recovery of the cost is provided for in Title XVIII of the Social Security Act.

The other essential transplantable tissues have no comparable federal support and over the years these have been procured, processed and stored in very few locations, usually at the request of the local professional staff.

While prospective donors may elect which tissues will be donated through the donor card mechanism and next-of-kin permission, their wishes may often be frustrated because the funding, the facility and the staff are oriented toward solid organ retrieval only.

It is the belief of our Association that federal support should also be available to full service tissue banks that will serve a broad medical need.

We believe that the nation's needs would best be served by the development of regional, full service tissue banks having a physical facility designed for that purpose, a trained and competent professional staff devoted full time to its operation, and a defined set of quality control and procedural standards to ensure the quality and reliability of its product.

We would urge federal support for the development of regional tissue retrieval and banking programs. The Public Health Service, in order to insure that optimum use is made of available funds should create a policy review group to oversee national efforts. We believe this is preferable to mandating a new federal program.

Voluntary organizations and non-profit institutions have been working on these problems for some time. The organ sharing network proposed by this bill for nationwide use has existing regional counterparts, for example, the United Network for Organ Sharing (UNOS). The newly formed American Council on Transplantation will attempt to coordinate approaches to donor recruitment. These efforts should be encouraged and expanded to include all useful human tissues rather than for solid organs alone.

The authors of the bill are to be complimented for proposing a national registry for transplants and for perceiving that only through documentation can the safety and efficacy of these procedures be evaluated.

The American Association of Tissue Banks also supports the provision prohibiting the sale of tissues or organs and has wording to the same effect in its own standards. However, while including the "reasonable costs associated with removal, storage and transportation" the bill fails to consider the reasonable costs of quality control, processing, and preservation which are equally essential to high quality organ and tissue transplantation.

While the humanitarian intent of this proposed legislation is beyond question, we feel that focusing primarily on the retrieval of organs will stultify medical progress by failing to encourage also the retrieval of multiple tissues.

We urge that H.R. 4080 be amended to provide:

Support for full service regional tissue banking and encouragement for the procurement of multiple organs and tissues.

Adequate storage and stockpiling of non-viable tissues.

Necessary quality control and quality assurance cost recovery.

Better utilization of donor resources through local and regional coordination of procurement and distribution.

Encouragement of educational programs for donor recruitment by voluntary organizations and local institutions.

Thank you for this opportunity to present our views and for your efforts in this cause.

Chairman JACOBS. Thank you, Doctor.

Mr. Snyder, will you proceed in your own manner?

STATEMENT OF A. H. SNYDER, JR., CHAIRMAN, LEGISLATIVE-GOVERNMENT AFFAIRS COMMITTEE, AND IMMEDIATE PAST PRESIDENT, EYE BANK ASSOCIATION OF AMERICA

Mr. SNYDER. Thank you, Mr. Chairman, I will be pleased to.

I appreciate the opportunity of discussing H.R. 4080 on behalf of the Eye Bank Association of America, which is an organization of 92-member eye banks that provide more than 20,000 corneas annu-

ally for corneal transplants, as well as sclera, which is the white of the eye, for other types of operations and donor eyes for research needs.

Report No. 98-575, which accompanied H.R. 4080, is therefore greatly in error in stating that some 5,000 "kidney transplants, in turn, amount to over 90 percent of the transplant procedures performed in the Nation." Report 98-575 indicates a lack of adequate study and understanding of nonbeating heart-type organ and tissue transplant fields.

Mr. Gore touched on this very briefly. The bill does not now differentiate between the disciplines; they are just tossed into the same basket.

In discussing H.R. 4080, it should be pointed out that the term organ is defined in the legislation as a human kidney, liver, heart, lung, pancreas, and any other human organ or tissue—including corneas, bone, and skin—included by the Secretary of Health and Human Services by regulation. Mr. Gore mentioned removing corneas, which really doesn't change the sense of the legislation at all. It would appear that the Secretary could even include human blood, if the Secretary so desired.

Title III of H.R. 4080 prohibits the purchase of organs, which is a policy we support. We appreciate Mr. Gore's comments concerning the expansion of reasonable costs which would be necessary to eliminate substantial problems for those processing tissue.

Title I, section 372 calls for the establishment and operation of a U.S. Transplantation Network which shall, among other things, have a board of directors which includes representatives of organ procurement organization described in section 301, that is, kidney procurement teams, transplant centers, voluntary health associations, and the general public; maintain a list of individuals who need organs, and establish and maintain standards of quality for the acquisition and transportation of donated organs and for tissue typing centers.

The specifications for the board of directors of the proposed Transplantation Network does not insure expertise in any organ or tissue transplant field other than kidney, and yet it is called upon to establish standards for all organs and tissues, if the Secretary so specifies.

Title I, section 371 states that the Secretary of Health and Human Services may make grants for the planning, establishment, and initial operation and expansion of qualified organ procurement organizations, and to expand the activities of such organizations.

A qualified organ procurement organization is defined as one which, among other things, has an agreement with the Secretary to be reimbursed under Title XVIII of the Social Security Act for the procurement of kidneys. The section specifies that a qualified organ procurement organization—that is, a kidney procurement team—will perform all those functions customarily done by organ or tissue banks in all areas of donor organ or tissue fields, at the pleasure of the Secretary, without regard to either the expertise or interest of the kidney team selected.

Even the possibility of H.R. 4080, with its promise of Federal funds, has created a very bad situation in the city of Phoenix, Ariz. This past Friday, Arizona Lions Eye Bank received promotional lit-

erature on an organization called the Phoenix Transplant Center, naming Ben A. VanderWerf—who was mentioned earlier today—M.D., Ph.D., as director. They advertise a 24-hour telephone service for all organ donations, including eyes.

A phone call that evening, Friday evening, determined that the 24-hour phone was answered by an answering service which had no knowledge concerning organ donations, and was simply taking telephone messages and advising the caller to call back on Monday morning during office hours. As you know, Dr. VanderWerf is a transplant surgeon, I understand, in the kidney and heart fields.

Unfortunately, it should not be surprising what the lure of potential Federal grants will do. It is our opinion that scenarios of this type will be frequent throughout the United States if H.R. 4080 is passed in its present form. That sort of confusion, and the lack of real understanding of nonbeating heart organ and tissue fields by kidney retrieval teams, and a lack of real interest in nonbeating heart organs by many kidney retrieval teams, will be disastrous to patients and researchers who now depend on viable, effective nonbeating heart-type organ and tissue banks that are now in place.

There are a couple of very simple things that can be done to do what we are looking for, and that is to increase the number of donors—very simply and at minimal cost. For instance, all hospitals receiving Federal funds could be required to have a question on the admittance form as to whether the patient is an organ donor. Hospitals don't like this. They don't like to think about that, so it takes a little pressure. A similar question could be required to be included in the standard questions asked of the next of kin on the death of a patient.

Medical schools and nursing schools receiving Federal funds could be required to give students an effective grief counseling course, which not only provides needed help to the next of kin, but also effectively increases the supply of donor organs.

ACT was mentioned this morning, the American Council on Transplantation. It was mentioned favorably and also derisively. It made a legitimate start, and it has overcome some problems. It has a long way to go. I think we have got to have a good, viable organization developed where organizations, such as the American Association of Tissue Banks, ourselves, interested persons from all areas of tissue banking and transplantation can work together in the private sector, with a minimum of Federal financial support, to solve the important and serious problem for which H.R. 4080 was proposed.

It is felt that the problems will be solved much more quickly, and at a much lower cost, without the Federal intervention proposed in H.R. 4080.

[The letter from Mr. Snyder follows:]

EYEBANK ASSOCIATION OF AMERICA,
Dallas, Tex., February 9, 1984.

To the Ways and Means Committee of the U.S. House of Representatives
Subject H.R. 4080 by Gore

In behalf of the Eye Bank Association of America and as Chairman of that organization's Committee on Legislative-Government Affairs, I have requested this opportunity to submit testimony concerning H.R. 4080 by Gore.

I have served on the Board of Directors of the Eye Bank Association of America since 1977 and as president of the organization in 1983.

My experience in the field of eye banking has come from serving on the Board of Directors of the Lions Sight And Tissue Foundation in Dallas, Texas, since 1971. I have had administrative responsibilities in that organization for 10 years and serve as its Executive Vice President.

I am a principal in a successful small business for which my background is in engineering and marketing.

The Eye Bank Association of America is an organization of 92 member eye banks that provide more than 20,000 corneas annually for corneal transplants as well as sclera for other types of operations and donor eyes for research needs. Report 98-575, which accompanied H.R. 4080, is therefore greatly in error in stating that some 5,000 "kidney transplants, in turn, amount to over 90 percent of the transplant procedures performed in the nation." Report 98-575 indicates a lack of adequate study and understanding of non-beating heart type organ and tissue transplant fields.

The Eye Bank Association of America is an ancillary organization to the American Academy of Ophthalmology. It has established standards for eye banks that have been approved by the American Academy of Ophthalmology. The Association inspects and certifies eye banks to those standards and it trains, tests and certifies eye bank technicians.

An eye bank is generally responsible for all activities concerning donor eyes or corneas from obtaining the donation until the cornea or eye is delivered to the operating room for a recipient or to an appropriate person or agency for research.

In discussing H.R. 4080, it should be pointed out that the term organ is defined in that legislation as the human kidney, liver, heart, lung, pancreas, and any other human organ or tissue (including corneas, bone and skin) included by the Secretary of Health and Human Services by regulation. It would appear that the Secretary could even include human blood if he so desired. In discussion, I have used "organ/tissue" rather than just organ. The legislation makes no distinction between beating heart donor organs and non-beating heart donor organs/tissues despite major differences in the disciplines involved.

Title III of H.R. 4080 prohibits the purchase of organs which is a policy we support. However, Sec. 301(c)(2) needs to be revised to read "The term 'valuable consideration' does not include the reasonable costs associated with removal, processing, preservation, quality control procedures, storage and transportation of a human organ." It would be assumed that the legislation, as written, intended the listing of "removal, storage and transportation" to include all of those reasonable and necessary costs but they should be specifically stated to insure no misunderstanding or unintended interpretation.

Title I, Sec. 102 calls for the establishment of a Task Force which would seem desirable. It is felt that in addition to conducting a national conference to consider specific organ/tissue transplant problem areas that it should thoroughly study all fields of organ and tissue transplantation and determine what is the appropriate involvement, if any, of the Federal government and how such involvement can best be accomplished before major legislation is sent to the floor. The Task Force should have more persons who are not physicians but who are involved in organ/tissue banking than the three members listed from the field of organ procurement. A figure of 9 would be more appropriate. Such a task force should discover there are some very simple things that could be done at minimal cost to increase the number of organ donors. All hospitals receiving Federal funds could be required to have a question on admittance forms as to whether the patient was an organ donor and a similar question included in standard questions asked next of kin on the death of a patient. Medical schools and nursing schools receiving Federal funds could be required to give students an effective course on grief counselling which not only provides needed help to next of kin but also effectively increases the supply of donor organs.

It would seem that such a task force would recommend that those receiving reimbursement under Title XVIII of the Social Security Act for the procurement of kidneys be required to solicit donations of all organs and tissues as well as beating heart type organs they usually solicit. Donations of non-beating heart type organ and tissues should then be referred to the appropriate organ or tissue bank. In other words, the Federally funded organizations should cooperate closely with those non profit organ and tissue banks that are effectively providing needed services without Federal funding.

Title I, Sec. 373 calls for the development and maintenance of a Scientific Registry of the recipients of organ transplants. Such information should be developed but

it can probably be best developed without additional legislation by cooperative efforts of interested government and private sector agencies already in place rather than by additional legislation and funding.

Title I, Sec. 372 calls for the establishment and operation of a United States Transplantation Network which shall, among other things, have a board of directors which includes representatives of organ procurement organizations described in Sec. 301 (i.e. kidney procurement teams), transplant centers, voluntary health associations and the general public; maintain a list of individuals who need organs; and establish and maintain standards of quality for the acquisition and transportation of donated organs and for tissue typing centers.

The specifications for the board of directors of the proposed Transplantation Network does not insure expertise in any organ/tissue transplant field other than kidney yet it is called on to establish standards for all organs and tissues if the Secretary so specifies. The maintenance of a list of individuals who need organs would develop into a red tape catastrophe if interpreted, as it easily could be, to mean a list of all individuals who need organ or tissue transplants whether it be a patient waiting for a kidney, a cornea, a bit of bone, a skin application or maybe even a blood transfusion.

I understand that the United Network for Organ Sharing (UNOS) is close to being a sufficient network for distribution and matching of beating heart organs and it has expressed a willingness to work with other transplant disciplines. It would appear that adequate additional funding to bring UNOS to an adequate level of service should be obtainable from the private sector without the injection of additional Federal funds. Through the cooperative efforts of members of the Eye Bank Association of America, including its computer network, corneas are being effectively distributed—not perfectly yet—but by the end of this year of 1984 waiting lists for corneas should be essentially a thing of the past.

Title I, Sec. 371 states that the Secretary of Health and Human Services may make grants for the planning, establishment, initial operation and expansion of qualified organ procurement organizations and to expand the activities of such organizations.

A qualified organ procurement organization is defined as one which, among other things, has an agreement with the Secretary to be reimbursed under Title XVIII of the Social Security Act for the procurement of kidneys. The Section specifies that a qualified organ procurement organization—i.e. a kidney procurement team—will perform all of those functions customarily done by organ or tissue banks in all areas of donor organ and tissues fields, at the pleasure of the Secretary without regard to either the expertise or interest of the kidney team selected in all fields of organ procurement, quality control, preservation, storage and distribution, excepting preservation and storage if they wish to "have arrangements" for those services "with tissue banks". Such kidney teams could be forced, if you will, into fields where they have neither interest nor expertise—in fields where viable effective organizations are now doing a good job. This sort of action would be a major set back to donor tissue availability and it would stifle research. Supporters of H.R. 4080 say such things would never occur but legislative and administrative history indicates otherwise.

For example, even the possibility of passage of H.R. 4080, with its promise of Federal funds, has created a very bad situation in the city of Phoenix, Arizona. This past Friday, February 3, 1984, our member eye bank there, the Arizona Lions Eye Bank, received promotional literature on an organization called the Phoenix Transplant Center naming a Ben A. VanderWerf, M.D. Ph.D., as Director. A 24 hour telephone service was offered for all organ donations including eyes. A phone call that evening determined that the 24 hour phone was answered by an answering service which had no knowledge concerning organ donations and which was simply taking messages and advising the caller to call back on Monday during office hours. Dr. VanderWerf is reported to be a transplant surgeon in the kidney and heart fields.

Unfortunately, it should not be surprising what the lure of potential Federal grants will do and it is our opinion that scenarios of this type will be frequent throughout the United States if H.R. 4080 is passed in its present form. That sort of confusion and the lack of real understanding of the non-beating heart donor organ and tissue field by kidney retrieval teams—and the lack of real interest in non-beating heart organ and tissues by many kidney retrieval teams—will be disastrous to patients and researchers who now depend on viable effective non-beating heart type organ and tissue banks that are now in place.

Through federations such as the American Association of Tissue Banks and the new American Council on Transplantation, organizations such as the Eye Bank Association of America and interested persons from all areas of organ/tissue banking

and transplantation are working together in the private sector with very minimal Federal financial support to solve the important and serious problems for which H.R. 4080 was proposed. It is felt that the problems will be solved much more quickly and at much lower cost without the Federal intervention proposed in H.R. 4080.

Respectfully submitted,

A. H. SNYDER, Jr., *Chairman,*
Legislative-Government Affairs Committee.

[Attachments to this testimony have been retained in the Subcommittee files.]

Chairman JACOBS. Thank you, Mr. Snyder.

Ms. Heck, you may proceed.

**STATEMENT OF ELLEN HECK, TRANSPLANT COORDINATOR AND
ADMINISTRATIVE DIRECTOR OF TRANSPLANT SERVICES, UNI-
VERSITY OF TEXAS HEALTH SCIENCE CENTER AT DALLAS**

Ms. HECK. Thank you, Mr. Chairman.

I appreciate this opportunity to talk to you today. I do, in part, echo the things that Dr. Stevenson said earlier. I am a transplant coordinator, and have been for a number of years. I am concerned that this particular bill is not going to help us with the issue that I think is most important to us, and that is getting more donor tissue available. I feel that the tissue has to be made available on a local level.

We have not had Federal funding with the tissues that we procure, and we have utilized a process which has incorporated civic and charitable organizations, along with the State and county governments. We feel that we have developed a fairly workable program which resulted last year in 467 combined donations. We also have an active research program for the delivery of pancreatic cells.

We realize that there are obstacles to organ donation in our city and in many other cities across the country, but we question and really do not believe that Federal legislation will help us to overcome these problems. In fact, we think that it may simply intensify them.

The limited scope and purpose of the original kidney legislation was interpreted to be so exclusive in a number of cases as to even preclude the asking for other tissues. Hopefully, any new program will recognize that such a limited scope and singular purpose is not in the best interest of our Nation's transplant needs, and that it would be a shame if any usable tissue is lost simply because no one asked for it.

We have found that 60 percent of the families that we were able to contact are willing to make organ donations, and they find that it is a helpful and positive experience for them in an otherwise negative situation. We feel that with additional public education and awareness, we will make even more organs and tissues available of all types.

Before any new legislation is passed, we also hope that you will examine the progress that we have made in the last few years in meeting the transplant needs and in developing standards. Through a variety of medical organizations, like the American Association of Tissue Banks, and the Eye Bank Association of America, standards have been developed to assure the quality of tissue procured is the highest possible, and that a surgeon in any part of

the United States may get a tissue from any other part of the country and be sure that it meets these standards.

We feel that the private sector initiative can develop a more cost effective and functional system by combining their efforts through the private sector with the civic and charitable organizations, and with the local governments, than can be developed through legislation or Federal funding.

Certainly, there are in this legislation a number of programs which we do support, particularly the one that has been mentioned most today. We do endorse the part of the bill that would outlaw the sale of tissue. We would welcome any legislation that would remove the taint of commercialism from the humanitarian spirit from which organ donation has arisen.

As you make the decisions about what must be done in transplant legislation, I will close by urging you to consider the things that you can do to benefit ongoing local programs, to encourage additional hospital participation, to unify existing transplant programs at least to the extent that they function together in securing permission for all usable tissues, and that a program of public and professional education be developed as a first priority.

Thank you.

[The prepared statement follows:]

STATEMENT OF ELLEN HECK, ADMINISTRATIVE DIRECTOR OF TRANSPLANT SERVICES,
UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT DALLAS

As the transplant coordinator and administrator of a transplant bank for ten years, I have been constantly concerned with making available enough tissue to respond to increasing medical needs. In addition, we have tried to make this tissue available in a cost effective manner and feel that we have, in part, accomplished these objectives by putting together at the University of Texas Health Science Center at Dallas an organ procurement program which has developed with a unique blend of private sector support from civic and charitable organizations along with a combined endeavor on behalf of the state and county government. Last year our program resulted in approximately 467 combined donations and also has an active research program for delivery of pancreatic islet cells.

Nevertheless, we realize that there are obstacles which must be overcome in our city and many other cities across the country in order to have adequate tissue availability. We do question, however, whether Federal legislation will help us to overcome these problems or simply intensify them. The limited scope and purpose of the original kidney legislation was interpreted to be so exclusive in a number of cases as to even preclude the asking for of other tissues. Hopefully, any new program will recognize that such limited scope and singular purpose is not in the best interest of the total transplant needs of this nation and that it is a shame if any useable tissue is lost simply because no one asked for it. We have found that 60 percent of the families we are able to contact, and I hasten to add that the majority of our initial contacts are by phone, are willing to donate the tissues and organs for which they are asked. They find that organ donation is a helpful and positive experience for them in an otherwise negative situation. With additional public education and awareness, we feel even more organs and tissues of all types will be made available.

Before any new legislation is passed, we hope that you will examine the progress we have made in the last few years at meeting the transplant needs and at establishing standards. Through a variety of medical organizations such as the American Association of Tissue Banks and the Eye Bank Association of America, standards have been developed to assure that the quality of tissue procured is the highest possible and that a requesting physician in any part of the United States may be confident that the tissue received from any other part of the country meets these standards. We feel that through the private sector initiative we are developing more cost effective and functional systems by the combined programs of the Universities, counties, state, benevolent and civic organizations than perhaps can be developed through additional Federal legislation or even Federal funding.

Certainly there are within this legislation a number of programs which we wholeheartedly support such as the formation of a task force which because of its national scope would be able with adequate time and research to gain a more comprehensive picture of what is needed in transplant today. Also, we endorse the parts of the bill which would outlaw the sale of tissue. We welcome any legislation which would remove the taint of commercialism from the humanitarian spirit from which organ donation has arisen.

As you make the very difficult decisions as to what must be done in transplant legislation, I will close by urging you to consider the things which you can do to: (1) benefit ongoing programs on the local level, (2) encourage additional hospital participation, (3) unite the existing transplant programs at least to the extent that they function together in securing of permission of all useable tissues, and (4) develop programs which promote public and professional education regarding transplant as a first priority. Again, let me thank you for the opportunity that you have afforded me to present this information to you today.

STATEMENT OF CHARLES R. BAXTER, M.D., F.A.C.S. PAST PRESIDENT, AMERICAN BURN ASSOCIATION

Identification: Chief of the Renal Branch, Institute of Surgical Research, 1956-58; Chief, Regional Dialysis Center, Parkland Memorial Hospital, 1958-64; Director, Regional Burn Center, Dallas, Tex., 1961-Present; Director, National Institutes of Health Burn Research Center, 1978-Present; Director, Clinical Tissue Transplant Bank of the University of Texas Medical School at Dallas; Past President, American Burn Association, American Association for the Surgery of Trauma; Member of, American Colleges' Committee on Trauma, American Colleges' Committee on Infection; Current President of the American Association of Tissue Banks, Skin Council; and member of the Board of Governors of the American Association of Tissue Banks.

I'm grateful for the opportunity to address the committee concerning House Bill H.R. 4080 since the bill addresses several of the issues of vital importance to the rapidly developing field of clinical tissue and organ transplantation. While timely in its presentation, it holds little promise of significantly increasing the number of transplants or in solving the problems of cost containment that are so devastating in certain areas of tissue transplant. Further, it inserts regulation and expense into areas where the private sector of medicine has made significant advancements. For example, the American Association of Tissue Banks has successfully completed, and approved, the standards and procedures for the procurement and quality control for almost all currently transplantable tissues. In January of 1984, the American Commission on Transplantation was organized as a professional and lay organization for the purpose of coordinating all transplant activities disseminating information to the public and raising funds for advancing all aspects of clinical transplant. Insurance companies are expanding medical policies to cover the cost of transplantations for livers, pancreases, and other organs. As of two months ago, one company in Massachusetts had secured 2/3d's of the clients necessary to assure viability of the first policy offered for transplant services.

Certainly one of the most advanced areas in the field of transplantation is that of kidney. However, the federal program for the care of chronic renal insufficiency has proven to be very costly and consumes a sizeable share of federal medical cost. The current cost of \$1.5 billion per year for this program furnishes treatment for 65,765 patients on chronic dialysis, 10,000 of whom were considered candidates for kidney transplant in 1983. Since the criteria for transplantation are not likely to change radically, even doubling the number of transplants will not make a significant dent in reducing the total yearly cost. Great excitement has been created by the discovery and early clinical use of cyclosporine A. This immunosuppressive drug while reflecting a significant step forward, not only has already been shown to have complications such as those producing organ failure in the patients own normal organs in some cases, but, more importantly, will not change significantly the transplantation criteria. Therefore the number of chronic care patients is not likely to decrease significantly.

Turning attention to the bill itself, Title I, Section 371 stipulates criteria for qualification of organ procurement organizations to obtain federal funds for the purpose of establishing or expanding procurement operations on a geographic basis. The major problems with this section are:

1. It does not safeguard the equal sharing of all the transplant organ groups in the procurement procedures within a region.

2. It does not force utilization of tissue banks from adjacent regions when they do not exist within the procurement area.

3. It stifles development of any procurement agency without previous Title XIII approval.

4. It does not define sharing of procedural cost between the various tissues being harvested.

5. It does not provide resources for training multipotential harvest teams that would reduce the cost of procurement.

6. No mechanism to assure participation of all hospitals in the procurement program.

7. No public education or teaching requirements.

A more carefully constructed revision of this section could insure procurement of all useable tissues, reduce procurement fees, and protect the advancement of transplantation in areas other than renal transplant.

Section 372, establishing a U.S. transportation network, as outlined, represents an unnecessary duplication of already functioning adequate matching systems. The local or regional accumulation of competent data is being carried out at all academic centers performing transplants.

The amendments recommended under Title II to medicare and medicaid are intended to encourage the development of clinical delivery transplantation centers. Certainly hospitals would respond to establishing transplant clinical services if reimbursement is adequate, but this does not solve the problem of qualified transplant surgeons and quality delivery of care of such a program. Further, the legislation totally ignores the transplantable tissues currently being funded by all types of third party carriers. The legislation would impose undue regulations on specialties such as ophthalmology, orthopedics, plastic surgery, general surgery, and other disciplines who routinely transplant bankable tissues.

The establishment of a task force to study the problems of tissue and organ transplantation is greatly needed and particularly before any definitive legislation is designed to meet all the existing problems in the area of transplant. Finally, Title III is to be applauded at the present time in order to prevent both commercialism within the donation of human tissues and to prevent inflicting physical harm to an otherwise normal population.

The legislation as currently written is to establish a national procurement service for all organs and tissues. At the considerable expense over a five year period. It would assume responsibility for an organ procurement system that needs only a moderate amount of help in several ways, none of which are specified in the current legislation. First, the bill centers on the acquisition of kidneys and livers and related solid organ transplants. It ignores 95 eye, 16 skin, 12 bone and other procurement teams currently operating within the transplant structure, many of whom are contributing heavily to the procurement of heartbeating donors. The already present tendency of renal procurement teams to ignore the other transplant needs will be enhanced by the current legislation. Further, the establishment of a national registry will not enhance the matching of donor to recipients sufficiently to warrant expense and to justify the regulations imposed in addition to the currently privately operated system. The registry, if expanded to include all patients receiving joint transplants, candidates for pancreatic transplants (2 million or more diabetic), would convert this into an unwieldy and extremely expensive operation. The unwritten plan for government control matching program would do little to enhance the current system that provides for the cost of typing locally of recipient candidates and computer matching by the national system. The need to further subsidize the cost of clinical transplant needs to be evaluated in the light of current trends in the insurance industry of offering transplant service plans and the subsidizing of new and unproven drugs requires considerable study before their coverage is enacted into law.

The major needs in the field of transplantation today are education of the lay and professional public on the benefits of transplantation; assuring hospital participation in donor procurement; reducing the cost in transportation for organ procurement; assuring acquisition of all transplantable tissues from each tissue donor when feasible, and research in the areas of improving tissue preservation and delivery and subsidizing the training of skilled physicians in the techniques of transplant and in investigational research to improve the field in every aspect.

(Submitted by Dr. Charles R. Baxter and Ellen Heck)

House bill H.R. 4080 and the accompanying report, submitted by Mr. Dingell from the Committee on Energy and Commerce, address areas of major medical concern and public interest and this demonstration of governmental attention will surely help to raise public consciousness to the need for more transplantable tissues and organs. There are, however, within these documents several areas about which we have questions and where we feel clarification or change may be appropriate.

Dividing the bill into its sections and addressing Part H—Organ Transplants, sub-sections (C) and (D) are, given the currently prevalent systems or organ procurement, almost totally restrictive and/or obstructive for the receipt of grants. The majority of existing organ and tissue procurement systems harvest either renal transplants primarily or non-heartbeat donors for skin, bone, eyes, etc. Therefore, these agents would not necessarily have or need systems for reimbursement for organs and tissues which are handled by the other program. Further, under sub-section (F)(I), definition of the Board of Directors is specific to the needs of "beating heart" donors, i.e. kidney, liver and not necessarily optimal for other tissues where a brain death pronouncement does not apply.

The development of United States Transplantation Network would appear to ignore the existing systems already serving transplant needs. These systems include the ham radio net for eye tissue placement, the Emory University eye placement computer system and the United Network for Organ Sharing used for renal tissue. These systems can be coordinated and expanded within their present structure through the private and benevolent systems through which they now operate. Also under (2)(D) the Transplantation Network would appear to intervene in a historically medical purview in the establishing of standards for donated organs. It is unclear how such a network would be qualified to establish medical standards or why they would wish to usurp the efforts and activities of such medical societies as the American Association of Tissue Banks and the Eye Bank Association of America already engaged in the drafting and implementation of standards.

Section 373 "Scientific Registry" again appears to be duplication of effort where such information is already available to large extent within the existing programs. Reporting of transplant information to the Secretary should be readily accomplishable through these channels.

Title II—Medicare and Medicaid. In this section we would like to join our opinions with those expressed by Blue Cross/Blue Shield. We support the efforts at cost effective payment for optimal service by limits to what facilities may be reimbursed for certain procedures which require a high degree of specialized service, equipment, and knowledge. Also, we too question whether or not the already burdened medicare system can and should be stressed with the additional payment obligation. We would encourage that every effort be made to pursue payment for organ transplant through a system within the private insurance sector.

Finally, under Title III we wholeheartedly support this effort of the government to assure that organ transplant remains clear of any controversy of commercial transaction via the buying and selling of organs and tissues.

In summary then, although we applaud the spirit of this legislation we urge careful consideration of its enactment in its present form. We wish to suggest to the legislature that other alternatives may exist which would accomplish the desired ends of making more transplantable tissues available without requiring such intrusion into the private sector or the expenditure of such sums of public funds. For consideration we submit the following suggestions, that the Federal government encourage:

1. Full cooperation of hospitals with organ procurement programs by asking hospitals to,

- (a) have donor information on hospital admit forms,
- (b) have a manual of organ procurement procedures and policies,
- (c) have and be able to supply documentation of cooperation with efforts and activity of total organ procurement.

2. All procurement programs to ask for permission for any useable organs and to be able to document compliance of same.

3. That an educational program be developed nationwide which has two primary objectives:

1. The increase of public awareness of the total transplant needs.
2. The education of medical and paramedical personnel to the organ donation process and benefits thereof as well as the compatibility of such donations with grief counselling.

(Such programs might be encouraged through review by Joint Commission or through those mechanisms used to assure lack of discrimination by facilities which receive federal payments.)

Finally, we recognize there is clearly a need for greater coordination of our efforts and hope the government will encourage and stimulate interest in the private sector to meet this need through steps similar to those mentioned above.

Chairman JACOBS. Thank you.

Mrs. Karsten.

STATEMENT OF GLEN W. KARSTEN, FOUNDING PRESIDENT, THE LIVING BANK INTERNATIONAL

Mrs. KARSTEN. Mr. Chairman and members of the subcommittee.

Thank you for inviting me. I think that it is interesting that at the very end, we are getting to organ donor education. We have talked about the medical side, and the most important part of it, of course, is to convince people that after death they should be organ donors.

During the flurry of heart transplants in 1968, it became evident that there was a crucial need for donors not only of hearts but all other types of tissues. Five women in Houston joined together to establish a nonprofit organization for the purpose of developing an awareness of the needs and to furnish the necessary legal documents.

The Living Bank was incorporated in 1968 with the goal of making it the usual, rather than the unusual, to be an organ donor. It was realized from the beginning that it would be pointless to educate people to be donors unless there was a network structured to facilitate the utilization of the donated organs.

At the very beginning, we set up a registry so that each member, as they signed up, would be computerized. We set up a 24-hour answering service, and a staff member was on tap at any time when a death occurred. The Living Bank, on notification of a death, contacts the nearest transplant center to the point that the patient died for whatever organ or tissue is medically acceptable.

There were no guidelines to follow but now, almost 16 years later, it has been proven that the original concept is the ideal way to interface the commitments and the desires of the general public with the needs of the medical community.

The Living Bank has never charged a membership fee. We have never received any money from the Federal, State or local governments. We have never even received any money from recipient institutions when we have called to tell of a potential donor.

The founders felt that when you donate organs, that is the greatest gift of all, you shouldn't have to pay to do it. So our support has come from an endowment, from corporations, foundations, and in a large measure from our membership, solely on a voluntary basis.

We have at this point over 125,000 registered members in all 50 States and 61 foreign countries. This doesn't count the thousands and thousands who sign a donor card and carry it with their driver's license, but don't return the donor registration form which we send to them.

The registry is the most vital function of the Living Bank. When a request for information comes, we send them a brochure. Each of you has a packet that gives all of our educational material. We

send the brochure which answers their questions, and a registration form that is in duplicate, so they can keep one and send the other one for the registry to be put on the computer. The donor card is to be carried with the driver's license.

When the donor form and the donor card are put on the computer, one of the things that we urge is that members keep us current about their change of address, their change of name, their change of next of kin, so at the time of death we will have the proper information.

The referral service is the maintenance of a referral directory which lists all transplant centers, organ banks, organ procurement coordinators, 24-hour numbers, and the current needs. This is being constantly updated.

We do not get involved in transplant suitability, or medical information, that is all done by the transplant teams. All we do is alert them to the fact that there is a potential donor, where the donor is, what the name is, and the telephone number of the hospital, or whatever.

We have a rather extensive education program. We have been working on educating emergency services personnel, police, firemen, all the people who might be involved at the time of death. We have visual aids available for that purpose.

The publicity is really one of the vital parts, I think, of donor education. The Living Bank has certainly had more than its share of it, because when we opened in 1968, we were on national television before we had an office. It was picked up by ABC News, and then Good Housekeeping published it within 2 months.

Since that time, all the major newspapers and the major magazines, then with President Reagan's radio appeal, giving our 800 number—amazingly enough, the people who read the columns are the ones that we hear most from. Dear Abbie, for example, has a tremendous readership, and we have been in her column since 1973 nine different times, and we will average 40,000 letters from that. Ann Landers has had it in hers, too.

It is absolutely astounding how many people are sold on the idea of organ donation because they read it in a column like this. We have had a lot of television coverage, too. Part of the point about this media coverage is that when you do an appeal like the President did, or like it was done recently for another child, it is not just that one child that is helped. It is the fact that the need for organ donation is brought before the public. With an 800 line, we are deluged with calls, and what they always say is: "I always wanted to know how to do this. Would you send me your material? This is something that I wanted to do, but I didn't know how."

Also you hear about potential donors, which the Living Bank does not restrict to the membership. We follow the same procedure with everyone. Three out of five calls that we get, incidentally, are people who are not members, but we follow the same procedure with the nearest transplant center.

There are certain policies that we follow, as I think all of us do, and that is, aside from having a person who is a donor or not a donor, is to observe the wishes of the next of kin at the time of death. If a next of kin is unhappy about it, or even uncomfortable at all, we don't press. I think that it is something that should be

done while the people are well and healthy, to talk it over with their next of kin and get the approval of their next of kin.

As far as H.R. 4080 is concerned, we feel very strongly that we do almost everything in the bill except for title III. We have been doing it for almost 16 years. We work very closely with every single organ bank, or organ procurement coordinator, all over the United States. We are working with the American Council on Transplantation. We work with these people at the table. We really do have a very good exchange of information, far better, apparently, than people realize. More organs are being retrieved all the time.

One of the things that you have to consider is that people are not going to be educated until they are ready, whether the Government tells them so or not.

In conclusion, I would just like to say that we do appreciate the concern of the Government, and we appreciate the desire of Congress to help alleviate the shortage of organs, but there is a system that is working. It is our belief that this program can be managed very reliably by the private sector.

Thank you very much.

[The prepared statement follows:]

STATEMENT OF GLEN W. KARSTEN, FOUNDING PRESIDENT, THE LIVING BANK INTERNATIONAL

Mr. Chairman and Members of the Subcommittee: Thank you for inviting me to appear before you today to brief you on the work being done by The Living Bank International. I am Glen W. Karsten, the Founding President.

During the flurry of heart transplants in 1968, it became evident there was a crucial need for donors not only of hearts but all other types of tissues. Five women in Houston, Texas joined together to establish a non-profit organization for the purpose of developing an awareness of these needs and to furnish the necessary legal documents with which the individual might make this commitment. The Living Bank was incorporated in 1968 with the goal of making it the "usual rather than the unusual to be an organ donor".

It was realized from the beginning that it was pointless to educate the public to be donors unless a network was structured to facilitate the utilization of donated organs. A registry was created for the computerization of the members and a 24-hour telephone service established. The Living Bank, on notification of a death, contacts the nearest transplant facility for the retrieval of any medically acceptable tissue.

There were no guidelines to follow but now, almost 16 years later, it has been proven that the original concept is the ideal way to interface the commitments and desires of the general public with the needs of the medical community.

The Living Bank has never charged a membership fee or a referral fee nor has any money been solicited from federal and state governments nor recipient institutions. The Founders felt that organ donation is the greatest gift of all and that no one should be required to pay to make this gift. Support has come from endowments, corporations, foundations and, in a large measure, the membership on a solely voluntary basis. The growth of the membership has been phenomenal and now, 1984, there are over 125,000 registered donors with hundreds of thousands carrying the donor card in all 50 states and 61 foreign countries.

REGISTRY

The registry is the most vital function of The Living Bank operation. When a request for information is received, a brochure is sent answering questions about organ donation as well as a donor registration form in duplicate and an uniform donor card. One copy of the donor form is to be returned to this office for the registry files and the duplicate is retained by the donor for their personal files. The donor card, when properly witnessed, is to be carried with their driver's license. Pertinent information from the donor form is entered on the computer and a con-

certed effort is made to keep all information current, i.e., next of kin, change of names, change of addresses.

Both donor card and form include name and address of next of kin, the donor's social security number, the 24-hour telephone number of The Living Bank and what the donor's wishes are regarding organ donation.

REFERRAL

Part of the service of the registry is the maintenance of a referral directory which lists all organ banks, transplant centers, organ procurement coordinators, their 24-hour telephone numbers and their current needs. This includes all of the 50 states and is being constantly updated. At the time of a death, trained staff handle the contacts with organ procurement coordinators, organ bank technicians, answer questions of the next of kin and offer counsel when requested by the family. Transplant suitability and all medical information is then developed by the transplant teams.

EDUCATION

A quarterly newsletter, "The Bank Account", is published for the membership and is an important tool for both education and communication. One issue always carries an annual financial report.

Interesting and productive special projects have been developed over the years with the purpose of educating emergency services personnel in the proper procedures for handling a potential donor. Visual aids have been developed which include "The Vital Link" film and manual, a police training film, posters and other educational materials. The project director works with Departments of Public Safety, firemen, police, medical examiners and paramedics using a round-table format to promote communication between these groups. "The Vital Link" is also being introduced into medical schools as part of their curriculum.

The Living Bank has available a 15-minute film, "Chords", a 6-minute slide show and a 27-minute film, "The Gift Of Life". Other educational tools are donor awareness drive kits, alert posters, hospital information kits, donor identification items such as a decal, pendant, keychain and a carrying case for the organ donor card and driver's license. A speaker's bureau handles requests from church groups, in-service for hospitals, service clubs, presentations to high schools and universities, health fairs and conventions. The personnel for this bureau is comprised partly of volunteers.

PUBLICITY

The public's need to know how to be an organ donor insured there would be immediate publicity about The Living Bank. Even before an office had opened, ABC Evening News carried a story and as early as December 1968, Good Housekeeping Magazine carried the name and address of The Living Bank as the source for an organ donor card. There has been a constant stream of articles since that time in most major national publications. Documentation will be supplied upon request. Television, radio and wire service coverage has followed The Living Bank since inception but 1983 was a banner year. Media appeals for liver donations giving the WATS 800 number of this organization swamped the staff but, with the help of volunteers, the requests for information were filled and numerous people were given new life with transplanted organs.

POLICIES

The Living Bank does not restrict their services to members. Three out of five calls at the time of death are about donors who are not members. When a call is received, whether from the next of kin, hospital personnel, ambulance drivers, police or as a result of a witnessed donation on a driver's license, the same procedure is followed. The primary reason for the existence of this program is to help others benefit through the miracles of medical science and to assist in seeing that the wishes of the donor and/or next of kin are fulfilled.

The Uniform Anatomical Gift Act has been passed in every state and enables a person to decide legally whether organ or whole body donations are to be made after death. However, it is the policy of The Living Bank to observe the wishes of the next of kin when there are objections. It is important to consider this question while healthy and with approval of family members. When this is done, no decision is necessary at the time of death.

SUMMARY

It is the feeling of the Board of Directors I represent that one feature of H.R. Bill 4080 should be enacted into law. This is Title III which addresses the subject of buying or selling organs. I am sure the Committee agrees with this but it clouds the issue to include that provision with the subject of transplant education and coordination.

The sponsor of the bill refers to "a patchwork of 110 different organizations" but there is only one multi-tissues and organ registry and referral service in the United States, The Living Bank. Testimony will reflect that a rather good exchange already exists between organ procurement groups and The Living Bank, the Lion's Club of America Eye Banks, Shriner's Burns Institute, the Human Growth Foundation, etc. This is even more evident during the occasional cases picked up by the media. As a result of appeals for one child, many others service desperately needed organs at transplant centers throughout the nation.

This is not to say that federal involvement is undesirable but merely an appeal to give the private sector the time to complete plans already underway. A second meeting of the American Council on Transplantation was held January 23 and 24, 1984 at which time a permanent organization was established with goals which duplicate the plans set forth in the Gore bill. The Council is composed of professionals in the transplant field, coordinating agencies, representatives from government, families with transplant experience and a wide spectrum of people who are involved at one time or other in some aspect of donor retrieval, utilization or education.

The American Council on Transplantation will function on public contributions and, at a time when federal budget deficits are at an all-time high, it is extremely important not to add to the burden which has already caused a staggering national debt. We should not denigrate the reliance the present administration desires to place on the private sector.

Transplants have been going on since 905 and will continue to take place while this subject is being debated. We appreciate the desire of members of Congress to help alleviate the shortage of transplant tissue. It is a concern The Living Bank has been sharing since 1968, but there is a system now and it works. It is our belief that management of this program can be reliably left in the hands of the private sector.

Thank you for your time and courteous attention.

Chairman JACOBS. Thank you, Mrs. Karsten.

Mr. Moore.

Mr. MOORE. There doesn't appear to be any need for the bill, if you are doing all of those things.

Mrs. KARSTEN. And I have been doing them for 16 years.

Chairman JACOBS. Thank you very much for your contribution.

The final panel consists of a representative from the New England Organ Bank, Dr. Benjamin A. Barnes, and the North American Transplant Coordinators Organization represented by Ms. Amy S. Peele.

STATEMENT OF BENJAMIN A. BARNES, M.D., SECRETARY-DIRECTOR, NEW ENGLAND ORGAN BANK, INC.

Dr. BARNES. Chairman Jacobs and Mr. Moore, I am very glad to be here to testify before this committee.

I am Dr. Benjamin A. Barnes from Boston. I am secretary-director of the New England Organ Bank, which has been involved in organ procurement for over 15 years. It was one of the first organizations to be started in this field. We now handle, as far as renal donors are concerned alone, about 120 donors. This means that we are processing 300 organs, including kidneys that are imported from other areas.

The New England Organ Bank is located in Boston. It represents the New England region. It is one of the independent organ procurement programs [OPA's], and for that reason it is not necessari-

ly representative of the rest of the country. I am sure you will take that into allowance in considering my remarks.

I thought, with your permission, I would not cover what I submitted in writing, but just make a few brief comments on some of the testimony given during this hearing, which I found intensely interesting and hope constructive for the purposes of considering this legislation.

To begin with, in our opinion, the OPA's are at the present time a Government program. They are not independent or examples of free enterprise. We are reimbursed by the ESRD program. Government auditors look over our books. The definition of reimbursable costs is made by these auditors, and by the financial intermediary that is looking at our operation. We have to have prior Federal approval of the fee we charge for the sale of kidneys to transplantation centers.

Therefore, I regard this legislation as an extension of a Government program, rather than a brandnew idea of intervention by a Government program into organ procurement.

I see this needed extension as helpful because we would have a national information system which we don't have now. We don't have, in spite of references to it, an agency which represents all organs, covers all transplant centers, and covers all donating hospitals. This doesn't exist. We have segments of it, but there is not one unified agency, and clinical transplantation interests have been trying for years to develop one. It has not come forth.

There has been no reason, no incentive in the private enterprise system to carry this load because, in fact, the dividends or returns here are not cash, but health care and the quality of health care. These are difficult things to cash in on. No one has accepted this entire ball of wax.

We think that such an information system would improve the standards of the content of information that is exchanged between the various communities and the various organ procurement agencies. At the present time, the information you obtain about donations is rather fragmented, and oftentimes you talk to one agency and you get one set of information from another agency, a different set of information. There is not a cohesive, overall, standard, uniform approach here in the exchange of information when you are trying to match up donors and recipients at the present time.

A most important point is that there are substantial variations at the present time in the equity of the distribution system. For example, you will not find potential recipients in different parts of the country having equal access to kidneys. It depends largely on the aggressiveness of the local agency and of the local transplantation unit.

There are many variables that influence this question of equity, and certainly at the present time there is substantial variation which we think would be reduced if you had a national information system which would give everyone far more equal access to the available organs than we have now.

Finally, I think there would be a contribution to education and improved standards if we had a national computer system which would cover this exchange of information and its development.

This would result in a substantial educational input to all of the units that are involved.

The proposed legislation provides incentives for having one organ procurement agency per region. I believe this is something, Mr. Moore, that you were concerned about, the possible closing out of various redundant agencies. This is precisely what has to be done.

What you have now in communities like New York, Philadelphia, Chicago, for example, are a number of competing agencies. It doesn't take long, in discussing with the staffs of these agencies, to understand that they are competing with each other. They have somewhat different programs, but too frequently overlapping and redundant functions.

In the communities they serve, there can be four or five groups competing to get organs and tissues, and there is a lack of standardization. This seems to fall short, I think, of a more ideal situation where you have, for each geographical region, one large organ procurement agency. This would lead to substantial savings. This is because each of the multiple agencies in general may have a preservation laboratory. You may have in a large urban community two or three preservation laboratories. You may have two or three tissue typing laboratories.

Tissue typing laboratories are involved in some of the most sophisticated techniques in modern medicine today. To have that information and that experience fragmented across a number of laboratories really is not the best way to obtain the highest standards and results.

From our New England point of view you want to have an aggregation of this into one regional tissue typing laboratory, so you have the benefit of substantial experience, which is illustrated perhaps best of all by Dr. Paul Tarsoski's operation in Los Angeles, where he has a very large and productive tissue typing laboratory.

Another advantage of having one organ procurement agency is that the donor families are subjected to one solicitation. We believe this is an extremely sensitive and important point. A family that is in the position of authorizing an anatomic donation from someone who is about to die, doesn't want to have four solicitors representing bones, eyes, skin, or heart. They would like to see one solicitation covering all donations.

The way you accomplish this is to have one organ procurement agency representing all organs and tissues approach the donor family at the appropriate time. This, we think, has been very much appreciated in the New England area.

Furthermore, each of the community hospitals that are involved in donations don't wish to negotiate with several procurement agencies for different organs and tissues. They prefer to negotiate with one agency which has a standard program that covers all organs and tissue. Consequently, in multiple donations, hospitals are dealing with one agency, and not with several.

We think the legislation is important in that it provides incentives and authority to bring about an aggregation of organ procurement agencies to avoid counterproductive competition and the inefficiencies of duplication.

We urge this committee to look very closely into the origins and accomplishments of the American Council on Transplantation

[ACT]. Many feel, and I am one of them, that it is very likely a front organization for current administration policies, and this is supported by the unusual admission that we heard today that the Federal Government is supplying lawyers for it, office space, and benevolent interest. This is suddenly a Federal program of sorts.

Why is this being done? We think it is being done in part because—if you get the reports from the recent American Council on Transplantation meeting, you will understand the general tone of the meeting and its deliberation—a preconceived goal of the council is to downplay the importance of Federal legislation and programs in this area. The motivation behind ACT should be carefully scrutinized by this subcommittee before accepting ACT as a neutral, independent agency that has complete freedom to view the legislation disinterestedly and decide on its merits as a free agent.

A final point is one concerning the designation of physicians and hospitals to perform transplantations. We think this an important issue and believe that the useful distinction can be made between certification of hospitals and physicians for performance, and the establishment of standards, which if met, would permit performance.

Standards can be established without identifying any hospital or physician. This is appropriate and already done in many circumstances in our society. Any physician and hospital that meet appropriate standards should be allowed to carry out the particular form of transplantation therapy. Establishing such standards might be helpful in alleviating the concerns that many have about a policy of certification of hospitals and physicians by the Federal Government. If there were rigorous standards, this would eliminate the threat perceived by a certification process.

I will be happy to answer any questions that you might wish to address to me.

[The prepared statement follows:]

STATEMENT OF BENJAMIN A. BARNES, M.D., SECRETARY-DIRECTOR, NEW ENGLAND ORGAN BANK, INC., BOSTON, MASS.

Witness: Dr. Benjamin A. Barnes of above address (tel. 617-732-5993) Secretary-Director of the New England Organ Bank.

Organizations represented: All organ procurement, preservation, and distribution facilities in New England as represented by the New England Organ Bank and the New England Council for Organ Donation.

SUMMARY OF RECOMMENDATIONS

1. Because of the continuing, acute shortage of organs and tissues for clinical transplantation, I recommend federal government support in grants to aid programs designed to promote organ and tissue donations. Non-governmental interests and free enterprise entrepreneurs have not identified organ donation programs a viable interest since the return is in health benefits, not cash income.

2. Because of the chaotic, uneven, and inefficient system now operating for the sharing of organs and tissues on a national basis, I recommend and support the concept of a United States Transplantation Network. This is needed to provide a public agency representing all donors and recipients on a national basis to optimize matching of donors and recipients for organ and tissue transplantation. The "regional blood sera match system" or, more understandably, a national laboratory for matching should limit its activities initially to providing donors for the highly sensitized patient. This target of highly sensitized patients is a small part of the waiting pool of recipients for organs, but they require exhaustive search amongst potential donors to uncover a recipient.

3. Because of conflicting views and programs developing under federal auspices, I support an office within the Public Health Service to coordinate federal organ and tissue transplantation policies. An example is the reimbursement policies for the care of dialysis patients that provide an incentive for physicians to eliminate a consideration of transplantation therapy for ESRD patients.

4. Because of the embarrassing discrepancy between the national records of the United States related to patients receiving transplantation and dialysis therapy and the excellent reports of the European Dialysis and Transplantation Association, I support a *scientific registry* of patients with the basic facts concerning their therapy and results. This is essential information for the federal government to have in order to monitor programs almost exclusively financed by federal entitlement programs.

5. Because of the inevitable development of interests in communities across these United States for transplantation, I recommend the development with collaboration and discussion with the medical profession of standards for centers conducting transplantations in regard to the selection of patients and in regard to the qualifications of the center for personnel, facilities, relation to community needs, and the like. The setting of national standards is desirable for maintaining high quality of care. The separate issue of cost control of medical care should not be addressed by federal programs limiting the number of institutions authorized to carry out transplantation therapy, but by programs capping total costs. This leaves the choice of hospital and medical profession activities to the local medical care system without dictating specific solutions.

6. Because of the need for a national review on an annual basis of transplantation policies and therapies, I support a task force with the mandate to review the medical, legal, ethical, economic, and social issues presented by human organ and tissue procurement and transplantation.

7. Because of the artificial and irrational division of payment for medicines and drugs on the basis of hospitalization or otherwise, I recommend outpatients having their medicines and drugs fully covered by federal programs if they are eligible for transplantation therapy in the first instance.

Chairman JACOBS. I think we will proceed with Ms. Peele first, and then see if there are any questions that can be propounded.

STATEMENT OF AMY S. PEELE, PRESIDENT, NORTH AMERICAN TRANSPLANT COORDINATOR'S ORGANIZATION

Ms. PEELE. You paint a very euphoric picture, and it is nice that you can do it in Boston, maybe some day in Chicago, in terms of regionalization.

I am going to be brief in my comments because I don't want to be redundant, and I realize that I am clean up here, so I would like to finish up. You have my testimony for the record, and I wish you would accept that.

Chairman JACOBS. Without objection.

Ms. PEELE. I just want to make a few comments. The group that I represent, North American Transplant Coordinator's Organization, is composed of over 400 coordinators throughout the United States, North America, and Canada. We are what you would probably refer to as the trench people.

We are the people who ask for organ donations. We approach the family. We orchestrate the events that culminate in organ donation, be it multiple or singular. We try to make it occur in a very professional manner, so that the grieving family is not feeling any more taxed than they already are.

We also have in our membership professional clinical coordinators who care for those patients who receive those organs, who teach them how to take their medicines, what to do now that they have a new lease on life.

That is the construction of our group.

When looking at the Gore bill, and we have for some time, we have supported it in general and we continue to support it. Under title I, in terms of the grant programs. It is nice to know that you can set up an independent organ procurement program and it will be funded by medicare, but that is after you receive or take a loan out for about \$125,000, which is not something that a lot of people can do.

The types of funds that they are talking about in this bill would promote an independent organ procurement agency in the areas that maybe it is not functioning. It would offer them a startup with those funds, and then to expand. There are also programs that could probably expand, but financially can't.

I understand that once a loan is taken out for the independent organ procurement agency, then each organ that is acquired through that has a certain amount of funds tacked on to it to pay for that loan on a long-term basis, so that you are not running in the red, so to speak.

The network that you, I think, Mr. Moore, referred to today, you asked about the United Network of Organ Sharing and the kidney sharing that occurs, and was there something similar in the case in terms of liver, heart, and lung.

Yes, indeed, there is and it is called the NATCO 24-hour alert system. It is a telephone line, and you access it simply by calling on the phone. Currently, it is in the process of being updated to a talking computer.

Pretty much, whenever we find that we have a donor anywhere in the United States—we, meaning procurement coordinators—before we approach the family to obtain multiple consent, we call that number and we get a listing of every patient in the United States who is waiting for a heart, a liver, or heart and lung.

That way, when we go to the family to have them sign the consent, we can tell them that Minnesota is going to take the heart, or Pittsburgh is coming to take the liver. It is sort of the tally list or the given that we have walking into a procurement situation to obtain consent, and then bring in the teams.

Since its inception, which was about a year ago, we have recovered about 122 livers through the use of that, about 93 hearts, and 2 heart and lungs, and these were transplanted at multiple centers. We found it to be extremely successful.

We have worked very long to get the funds to computerize it, so that it is much more efficient than it currently is. We are very pleased with the progress.

The network that is spoken about under the bill probably, if you want to look into the crystal ball, would include the UNOS system, the computer system in the NATCO 24-hour alert system, which is the phone system, both of which probably don't have the funding currently to own it, to continue to put it under a national framework, and make it available at a low cost to everybody.

In terms of the task force, it is really vague as to how it would function, but I think one thing that is very important here is that we need to get some bottomline numbers—how many kidneys, how many hearts, how many livers are we going to need, and how many potential recipients are there going to be, and what is the feasibility.

ty. This may be something that this task force could get their hands on and get back with numbers.

It would be unfortunate if the Congress were accused again, as they were in 1972 after they passed the ESRD legislation, of medicareless in granting funds from medicare to pay for the ESRD program, not really knowing well what the expenses were going to be that they incurred. I think that they far outweighed what they actually had thought that they would.

In terms of allowing extra programs to do transplantation, liver specifically and heart, we see that there is definitely a need for other programs. In 1982, Pittsburgh did get enormous numbers of calls to the tune of 523 offers for livers. Eighty of those were only used, and the rest of the calls were passed on to the other 14 programs that perform extra-renal transplants.

There is a problem because, as Dr. Starzl has already referred to and other people, when you call the program that is doing the extra-renal transplant, the team may be exhausted, they may be in the process of retrieving another organ, or they may not have a bed in their ICU to accommodate the recipient, all of which are things that could be solved if other programs started doing extra-renal transplantation.

Last, in terms of the buying and selling of organs, we suggest that that definitely be supported. It would be unfortunate to see that take place. The Blook Commission, I believe, or the American Red Cross, I forget where the origin was, did see a dramatic drop when blood was being bought and sold, and it took them a long time to recover in terms of voluntary donations.

One thing that probably could be done without any legislative effort is to encourage a joint commission on accreditation of hospital to include in all the hospitals that are accredited by them that when brain death occurs, or a death in the hospital, that the family be approached about organ donation to continue receiving medicare funds.

These are pretty much all the comments I have. If you have any questions, I will be glad to answer them.

[The prepared statement follows:]

STATEMENT OF AMY S. PEELE, PRESIDENT, NORTH AMERICAN TRANSPLANT
COORDINATOR'S ORGANIZATION

Representative Jacobs; Members of the Committee: My name is Amy S. Peele, President of the North American Transplant Coordinator's Organization (NATCO) and Senior Transplant Coordinator at Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois. I welcome the invitation to testify before this committee on behalf of the members of NATCO.

The North American Transplant Coordinators Organization (NATCO) is a national, non-profit organization representing over 400 professionals in the United States, Canada and several foreign countries. Our dedication is "That there be a better quality of life for the thousands of patients with end-stage organ failure. . . and a respect for those who shared."

The members of NATCO represent various aspects of the transplant community, including physicians, nurses and allied health professionals working with the organ recipients and those whose main objective is to obtain and distribute the valuable human organs and tissues so desperately needed by the waiting victims of end stage organ failure. NATCO members provide information to medical personnel and to the general public regarding all aspects of organ transplantation. In addition, NATCO disseminates information to its members concerning new techniques in organ procurement, preservation and transplant surgery.

The role of transplant coordinators varies greatly across the country according to the needs of the institutions for which they work. Some coordinators only deal with the recipient, assisting physicians with determining a patient's medical suitability for transplant, arranging for necessary laboratory and diagnostic testing, communicating with other health care providers (physicians, dialysis units, etc.) to keep current on the status of the patient, providing for the collection of frequent blood samples for tissue matching with specific donor organs, and educating and preparing the patient emotionally and otherwise for the future transplant procedure.

Procurement coordinators are specifically responsible for organ recovery. This includes developing a network of hospitals within a geographical area whose staffs will refer donors for organ and tissue recovery. The coordinators travel to these hospitals to meet with administrators, medical boards, nursing and other ancillary personnel to assist in formulating policies and procedures for the determination of brain death and organ donation. Frequent surveillance visits and continuing-education programs are offered as a means of keeping organ donation "alive" in the minds of the professionals in these hospitals. Procurement coordinators develop protocol manuals, posters, slide shows, telephone stickers, etc., for distribution in hospital emergency rooms and critical care units, the places where donor identification is likely to occur. A procurement center has a 24-hour "hot line" and a coordinator is available day and night to assist the donor hospital with the legal issues, medical management of the donor, obtaining consent from the appropriate next-of-kin, and organizing the surgical team for the recovery of organs and tissues.

When the organs or tissues are obtained, coordinators may be present in the operating room to help in the preparation and preservation for transplantation. Within the transplant center they may arrange for the final cross-matching and then admission of the suitable recipient. If the organ cannot be used by the local transplant program, the coordinator, using a national computer system, may arrange for the sharing and transporting of the recovered organ to another center—all in a time period short enough to ensure its viability.

Needless to say, one person cannot handle all the responsibilities described and many programs have a few persons hired under the general title of Transplant Coordinator. It must be recognized, however, that these centers work under conditions of extreme austerity and coordinators have learned to tap all available resources to ensure the efficacy of their programs.

With the Medicare involvement for end-stage renal disease in 1972, a network of procurement agencies were established throughout the entire United States. Since that time, there has been a mechanism established across the country to obtain and distribute cadaver organs and tissues for transplantation.

The National Organ Transplant Act can improve and expand that organ sharing systems thereby allowing thousands more end-stage organ disease patients another chance at life that only a healthy donor organ can bring.

Title I of the National Organ Transplant Act authorizes a program of grants for the development and expansion of local organ procurement organizations throughout the nation and the establishment of U.S. Transplantation Network. In theory, this is an excellent idea, however, the application of those funds to these organizations should be appropriated with careful consideration to the potential recipient organizations.

The establishment of U.S. Transplantation Network would possibly include two national systems currently existing: The United Network of Organ Sharing—a computer that prints out most recipients awaiting a kidney and the NATCO 24-ALERT system.

The NATCO 24-ALERT system began on September 23, 1982. This system, accessed by telephone, gives the caller a listing of urgently needed livers, hearts and heart/lung combinations from the 15 transplant centers that perform these operations across the United States and Canada. This system is not in competition with the computerized United Network for Organ Sharing.

Since its inception one year ago, the 24-ALERT system has facilitated the transplantation of 122 livers at 9 centers, 73 hearts at 9 centers and 2 heart/lung combinations at 2 centers. The system's success is due to the fact it was designed by transplant coordinators to meet their specific needs. It is also successful because it's easily accessed by telephone. This telephone system can complement the computerized system mentioned as part of the National Organ Transplant Act.

NATCO supports the establishment of a Task Force to study carefully the various issues surrounding the field of transplantation. It is important that a clearer picture be obtained regarding the number of possible patients needing extra-renal transplants and the potential of available donors to meet those projected needs.

Title II of the bill revises title XVIII of the Social Security Act to permit the Secretary to pay for organ transplants and other investigative procedures at a limited number of specialized centers.

NATCO strongly supports this provision of the bill because it will increase the number of medical centers performing extra-renal organ transplants across the country.

There has been much discussion over the past several months about the lack of donor livers for transplantation. The reality is that the University of Pittsburgh received 523 calls alerting them to the availability of donor livers in 1982. Only 80 of those livers were recovered and transplanted by the Pittsburgh program. 102 of the donor livers offered were declined by the Pittsburgh group because the transplant team was exhausted or the hospital could not accommodate another liver transplant patient.

So the shortage of donor livers is not as dramatic as portrayed by the news media. It is the lack of adequate liver transplant programs that precludes a larger number of patients from receiving therapeutic liver transplants.

Exempting organ procurement activities from the Medicare prospective payment plan shows a great deal of foresight on the part of Representative Gore. This action will continue to support the present system and allow for its growth.

NATCO strongly agrees with Title III of the bill prohibiting the sale of human organs and the penalties for violating this act.

The voluntary system of organ donation does work, buying and selling kidneys will only complicate the system not to mention the unethical aspects associated with this issue.

Our final recommendation to this committee is to suggest that the federal government, through the Joint Commission on The Accreditation of Hospitals (JCAH), mandate the establishment of policy and procedures in every hospital for the declaration of brain-death and for the referral of organ and tissue donors for transplantation. JCAH should require that upon every death in an accredited hospital, the deceased's next-of-kin be asked their position regarding organ and tissue donation.

In closing, I thank you for the opportunity to discuss NATCO's position regarding the National Organ Transplant Act.

We, as coordinators, are aware that although a successful organ procurement system exists, there is need for improvement and expansion. The National Organ Transplant Act with our recommendations can bring about this improvement and expansion especially in the areas of public education and professional participation in the transplanting of human organs and tissues.

Chairman JACOBS. Thank you.

Mr. Moore.

Mr. MOORE. Thank you, Mr. Chairman.

Ms. Peele, the bill does call for the establishment of a task force on organ transplantation to conduct a comprehensive study, or study the very question you have raised. Would it appear to be more prudent for us to legislate perhaps a bill that would prohibit the sale of organs, and to set up a task force like this to find out what we are getting into, rather than pass a bill that regulates everything before we know what we are getting into?

Ms. PEELE. In logic, that sounds very good, but I think there are a lot of patients right now who are suffering because they can't afford cyclosporine or transplantation. Some kind of effort needs to be extended, possibly legislatively, to at least start initiating or embarking on that journey, probably at the same time working with the task force.

Mr. MOORE. I see those questions as separate. There is no question that this Congress can address what it is going to pay for at any time, and we can do that. That to me is not so serious a question as having a better understanding of what we are getting into. Dr. Barnes stated he is strongly in agreement with moving ahead. I can understand his logic, even if I disagree with his conclusion. I wish my colleague, Mr. Rangel, had been here to hear how you

very clearly say what the bill says, and that is my reading of the bill, too.

I just hate to tell Ms. Karsten that her 16 years worth of work is going out the window, because when I look at Houston, I see that there are two organizations there doing the same work. We have to choose one of the two. I don't want to be the one, and I don't think that HHS either wants to be the one to tell her that she is out of business.

There are too many people doing the soliciting, and there are too many people doing the collecting, I think that this was Dr. Barnes' statement. He suggested that we have to get down to a regionalized process in which one agency is doing that. To me this means that the Government, through its certification program, has got to tell others to get out of the business. I am not really sure that we ought to do that without at least having the task force look into this deeper.

This was my question, doesn't the task force seem to be more logical to approach before we start getting into all of this certification business? We have the administration saying it doesn't want to do it, and many of us have grave questions about the necessity of doing it.

Ms. PEELE. I follow your logic, but I think that it is a stalling tactic. I think that they need to get into it, but I think they have to come across with, either we are not going to do it, or we want to study it, and that is what we are going to do again. We are not making too much headway in terms of coming up with answers.

Mr. MOORE. I think the progress you all have made has been astounding, and it is very promising, it is very helpful. We are not living in a perfect world where every patient has got a donor. Don't think that the Government is going to create that perfect world, just look at some of the other programs that we have looked at, and draw that conclusion.

Dr. Barnes, did you want to say something about my using your name in vain?

Dr. BARNES. I think the map here locating the organ procurement agencies really illustrates the problem. If you were trying to devise a distribution of organ procurement agencies on some rational basis, it wouldn't have the chaotic scatter that you see. Something has to be done to get them working together. It is really a multiregional operation. You can't have five in one or two counties, and it really doesn't make sense because of the elaborate nature of the operation of a tissue typing laboratory and the costs of redundant preservation laboratories.

We think the existing interests in organ procurement that we have heard today about are just that: they are very strong, parochial interests. Someone with authority, and we see none except the Federal Government, has to bring these groups together and provide incentives to work together. The fragmentation will continue indefinitely as at present unless there is some incentive provided, and I only see it coming from Washington.

Mr. MOORE. You may be right, but I sure would like to see a task force stating that before we pass a bill saying what we have to do. The simple reason is my concern over undermining the motivation that caused Mrs. Karsten, and the other individuals and organiza-

tions here, to do their work. We are then telling them, thanks, but no thanks, we don't need you anymore. We are going to have another group carry out these activities.

I see the same problem with raising money for universities. We can claim that there is too much diffusion in raising money for private universities, so we are going to have the Government determine that there is going to be one organization in a region that going to raise money for all the colleges around the country. It is not a lifesaving thing, but how we educate our children is very important. We raise money, and all kinds of people do it differently.

I am just yet unconvinced that the Federal Government has to come in and solve what I consider to be certainly growing pain problems, but not problems that require the heavy hand of the Federal Government. I am just not convinced of that yet, although I am totally in sympathy, and I don't think you are going to find anybody on this committee who doesn't agree 100 percent with what you are trying to get at. Where we part company, at least I do, is over the necessity of the Federal Government doing it for us.

I will go along with the study, this task force to look into it. If the study comes back and says, Congressman, you are all wet, we have got to tell Mrs. Karsten to get out of business, maybe then I would think about it. She is a nice lady, and she is doing a great job. I hesitate to have the heavy hand of the Federal Government get involved in that.

I have seen the Federal Government operate, and I am not fully impressed, to say the least, with what it has done so far in terms of helping people.

Chairman JACOBS. I would have to say this, Henson, in the U.S. Government versus Mrs. Karsten, I think she would win. [Laughter.]

Thank you for your testimony.

[Whereupon, at 2:20 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

AMERICAN ACADEMY OF PEDIATRICS,
Los Angeles, Calif., May 3, 1984.

Hon. DAN ROSTENKOWSKI,

House of Representatives, Rayburn House Office Building, Washington, D.C.

DEAR MR. ROSTENKOWSKI: The American Academy of Pediatrics would like to submit the following comments on H.R. 4080, the National Organ Transplant Act.

1. *A Task Force on Organ Transplantation.*—H.R. 4080 specifies that a task force be appointed by the Secretary of HHS to conduct, in a timely manner (one year), "comprehensive examinations of the medical legal, ethical, economic and social issues presented by human organ procurement and transplantation." Because volume and variety of organ transplantation seems likely to increase, it seems wise to plan nationally for access, funding, quality control, evaluation, and other aspects of transplantation.

H.R. 4080 does not specify the resources to be made available to the Task Force. Although the charge to the Task Force in Section 102(a) is quite broad, only the questions of access to transplantation, allocation of organs and payment for non-renal transplants are specified. These will be addressed in a conference, the report of which appears to be the only communication specified between the Task Force and the Secretary. It would seem desirable to specify technical support and budget for the Task Force (e.g., CDC, IOM, RAND, Battelle) and to have the Task Force to address all the areas identified in its charge. Without these provisions, the Task Force could not make a substantive contribution.

Physicians (such as pediatricians) who are not involved technically with organ procurement and transplantation should be considered for membership in the Task Force in order to represent other areas of health care which may be affected as a

consequence of increasing emphasis within the U.S. health care system on transplantation.

2. *Efficiency of Organ Procurement.*—The Academy supports enhancement of efficiency of organ procurement by provision of procurement activities which a) occur within given geographic areas (rather than centralized nationally) so that procurement can occur in a timely manner and b) are coordinated between geographic areas to promote full use of donated organs. The provision of financial assistance to organizations which show they represent the majority of potential donors in a specified service area and which will participate in the proposed U.S. Transplantation Network seems a reasonable way to improve organ procurement.

3. *Transplantation Network.*—The Academy endorses measures to enhance efficiency and equity in organ procurement and distribution. A computerized network is conceptually attractive, but the need for such should be documented. Anecdotal or even quantitative statements about unused donated organs are not indications, *per se*, that a Network would have allowed their use. It does seem likely however, as organ survival times *ex vivo* are extended by technical advances, that there will be more opportunities for use of organs outside the areas in which they were donated and thus there will be increased need for national coordination. Because there is no present consensus among many persons associated with organ procurement and distribution as to the need for a super-agency to coordinate procurement and distribution, this subject should have high priority for investigation and decision by the proposed Secretary's Task Force.

Specification of functions of the Network, as now done in H.R. 4080, may be premature and prove inflexible if given the force of law. Perhaps the functions noted should be presented as examples and provisions should be made for their modification as needs and technology may change.

In testimony before Congress, Secretary Brandt suggested that the American Council on Transplantation (ACT) would perform functions similar to those envisioned for the H.R. 4080 Network. This seems unlikely. ACT is an organization of individual members without qualifications for membership. Its Board of Directors is composed of persons with various professional and other identities but does not represent organizations or defined constituencies.

The Network appears to be a permanent federally supported function. Eventually, if it is necessary and effective, its costs should be part of transplantation cost. Freedom from direct federal support would provide the Network with more independence which might be desirable.

4. *Quality of Transplant Services.*—The Academy supports enhancement of the quality of transplant services. The volume of patients, qualification of personnel and kinds of facilities are likely to influence the success rate of transplantation as they do other high technology procedures in medicine which have been shown to achieve best results when there is a volume of patients sufficient to maintain the skills and organization of the health care providers and to justify maintenance of the extensive equipment and institutional resources necessary to support the technology. It seems reasonable for the federal government and other third parties paying for high technology care to establish reimbursement requirements to assure high quality of services purchased.

H.R. 4080 in Title II, Section 201 empowers the Secretary of HHS to establish criteria for payment for health care technology or procedures which specify medical criteria for patient selection and designation of treatment centers as acceptable. The legislative report about Section 201 describes the present law and practice concerning Medicare coverage determination. Presently the Secretary allegedly obtains advice and recommendations of HCFA, PHS, NIH, FDA, medical specialty societies, the medical community and others about designation of benefits which are or not reimbursable. This seems a reasonable way to decide what items and services will be reimbursed under Medicare.

H.R. 4080 does not limit the Secretary to establishing criteria just for transplantation but extends this power to other kinds of care. Because there are no proven valid methods for making such judgments, it would seem desirable for the Secretary to receive assistance from no fewer advisers than are stated to be used now, e.g., HCFA, PHS, NIH and medical specialty societies. Consultation with these advisers should be mandatory. Pediatricians should be among the non-surgeons who provide advice to the Secretary because funding decisions about transplantation affects availability of resources for other health purposes.

One of the strengths of H.R. 4080 identified by its supporters is that Section 201 allows evaluative trials of new technologies before the federal programs accept or reject them for reimbursement. This seems highly desirable. However, according to the legislative report which accompanies H.R. 4080, the Secretary now has this

power but has been reluctant to exercise it. If this is so, even if H.R. 4080 specifies this power, the Secretary may not choose to exercise it. The problem, it appears, is not authority but the will to exercise it.

5. *Payment For Immunosuppressive Drugs.*—The Academy endorses payment for outpatient immunosuppressive drugs. The high cost of Cyclosporine, which is not covered for outpatient, prevents some patients from obtaining this drug when it has been judged medically desirable. The provision of H.R. 4080 Title II, Section 204(a)(3), would therefore seem desirable. The limitation of payment to 36 months does not seem rational, medically.

6. *Purchase of Organs.*—The Academy opposes purchase of organs and thus should support the intention of H.R. 4080 Title III, Section 301. Section 301 should be reviewed to find ways to avoid punishing well-meaning, innocent persons.

7. *Registry of Organ Transplant Patients.*—The Academy supports scientific evaluation of transplantation. Section 373 provides for development and maintenance of a scientific registry of the recipients of organ transplants to provide evaluation of therapeutic success, medical complications, cost and other outcomes. Registries have had wide but often disappointing use in chronic disease programs. A common experience is that cost outruns the resources of the registry as numbers of patients increase and follow-up periods lengthen. Eventually operators of the register recognize that because of resource limitation the registration is incomplete and out of date. The register value falls.

While it is highly desirable that transplant patients be followed long-term to answer specific scientific questions about consequences of immunosuppression, restoration of function, medical complications, psychosocial problems, cost benefit and cost effectiveness etc., a register may be only one way to accomplish this. Section 373 might better specify the need for evaluation and then identify funds to be used for this purpose—dispersed through the National Center for Health Services Research or some other sponsor of scientific research within HHS. As Section 373 now stands, commitment to a registry may be quite costly, never ending and consume large amounts of money which could be spent for other kinds of evaluation.

In summary, the Academy would like to commend you for recognizing the current problems with transplantation and supports H.R. 4080 with modifications as outlined here.

1. The Task force appointed by the Secretary of HHS should be provided substantial technical and professional assistance so that it can make substantive and valid recommendations. Although the Task Force should have a mandatory one year time for its initial report, it might be maintained indefinitely as advisory regarding organ transplantation to the Secretary and the office established within the HHS. Provisions should be made for regular meetings, staffing, and rotation of membership. A pediatrician should be a member of the Task Force.

2. Financial assistance should be provided to develop regional organ procurement entities as outlined in Title I.

3. The options for structure and function of a Transplantation Network should be expanded so that such a Network can be maximally responsive to changing needs of patients and providers.

4. Title II Sec. 201 should specify the consultants to be used by the Secretary in arriving at decisions about reimbursement for new technologies. The AAP should be among those consultants.

5. Payment for immunosuppressive drugs for outpatients should be supported. There should be no time limit stipulated although provisions should be made to review the payment policy periodically to keep it current with state of the art.

6. Provisions to prohibit sale of organs should be supported. Specific wording of H.R. 4080 Title III should protect innocent participants.

7. The provision for a patient registry should be broadened to provide support for evaluation of transplantation outcomes by a number of means.

We would be willing to assist you in addressing the financial aspects of this issue, in particular, the widespread ramifications of using Medicaid funds for payment for transplants in children. Any funding mechanism needs to be carefully crafted.

Sincerely yours.

PAUL F. WEHRLE, M.D.,
President.

THE AMERICAN ASSOCIATION OF NEPHROLOGY NURSES AND TECHNICIANS,
Pitman, N.J., February 24, 1984.

JOHN J. SALMON,
*Chief Counsel, Committee on Ways and Means,
 U.S. House of Representatives, Washington, D.C.*

DEAR MR. SALMON: The American Association of Nephrology Nurses and Technicians is pleased with continued Congressional efforts in the areas of organ procurement and transplantation. While we, too, see a need for improvement in the areas of organ donation, procurement and placement, we recognize the tremendous advances made by many dedicated professionals in the field over the last thirty years.

We send our Association's support to H.R. 4080. It contains many of the suggestions our organization made last year regarding the important and necessary components of a national organ procurement system.

Our organization is equally concerned about the cost of the End-Stage Renal Disease Program to the American taxpayer and the status of the Medicare Trust Fund.

In light of the Congressional Budget Office Report and input from portions of our membership, we believe coverage of out-patient immunosuppressive medication to be a cost-effective expenditure. Given the fact that it costs far less to maintain a patient on such drug therapy following successful transplantation than it does to provide dialysis, this precedent-setting Medicare coverage of out-patient medications can be justified as none other.

We recommend, however, that consideration be given to the provision of Medicare benefits for coverage of immunosuppressive drugs only in the absence of or as an adjunct to private insurance coverage for out-patient medication.

Our Association sincerely appreciates the opportunity to have input to your committee on this and other issues relating to the End-Stage Renal Disease Program. Thank you for your consideration of our ideas.

Sincerely,

MARY BAKER, R.N., M.S., *President.*

AMERICAN COUNCIL ON TRANSPLANTATION,
Washington, D.C., February 27, 1984.

Hon. ANDREWS JACOBS, Jr.,
Chairman, Subcommittee on Health, House Ways and Means Committee, U.S. House of Representatives, Washington, D.C.

DEAR CONGRESSMAN JACOBS: It has come to my attention that your Subcommittee held hearings on H.R. 4080 (The National Organ Transplant Act) on February 9, 1984. During the course of testimony, several references were made to the American Council on Transplantation, such that I feel it would be of interest and importance to supply you and your colleagues with background information descriptive of the Council. It is my impression that the record for this hearing is still open, and I am therefore submitting for inclusion in that record this letter and a copy of my remarks as Interim President on the occasion of the first Annual Meeting of the American Council on Transplantation, held in Washington, D.C. January 23-24, 1984. My address summarizes the genesis and goals of ACT, provides a summary of our current national transplant program and areas that I, personally, feel require attention.

The American Council on Transplantation has not taken a policy position on any pending transplant legislation. This reflects the fact ACT is an independent federation of individuals and organizations from all areas of transplantation, the first on-going effort of this nature available to the transplant community. As such, individual organizations have had and continue to follow their own particular agendas and points of view, and this has led to honorable but divergent opinions concerning specific portions of the pending legislation. Indeed, you have heard differences of opinion expressed from numerous sources during the course of testimony, and all of these perspectives must be carefully considered by a forum such as the American Council on Transplantation before policy can be decided.

In summary, I think the background information pertaining to the American Council on Transplantation will be of use to the Subcommittee, and I am certain you will give your individual witnesses the careful attention they each deserve. If I can be of any further help in providing additional clarification or information, please do not hesitate to let me know. I am also assuming this information will be distributed to other members of your Subcommittee.

Sincerely,

GARY E. FRIEDLAENDER, M.D., *President.*

Enclosure.

PRESIDENTIAL ADDRESS—AMERICAN COUNCIL ON TRANSPLANTATION

I have approximately 20 minutes to summarize the genesis, present state and future directions of the American Council on Transplantation. This requires a bit of background information, definition of goals and early organizational efforts, some indication of what ACT is—and what it is not and, finally, some personal thoughts on the future. The entire story is lengthy, despite the short 4-month history of the Council, but I will spare you many of the details and hope the essence of my extreme joy and gratitude as well as some frustration will not be lost from my summary. After all—"all beginnings are hard." Dr. Benjamin Baker, the Interim Executive Director of the American Council on Transplantation, provided the title "Act One" for this address—perhaps "Round One" would have been more accurate. As far as I can tell, however, this is the only miscalculation Ben has made since joining ACT in December; and I will get back to thanking him more properly in a moment.

Onward. First, the good news. Our scientific, surgical and medical expertise has made it possible to transport numerous tissues and organs with such satisfactory and predictable success that for many individuals this approach must be considered a therapeutic option and, in some cases, the treatment of choice. We will be treated to a brief review of these accomplishments later this morning by outstanding purveyors of the art! [Heart/Lung, Phillip Oyer, M.D.; Kidney, Oscar Salvatierra, Jr., M.D.; Liver, Thomas Starzl, M.D.; Pancreas, David Sutherland, M.D.; Blood, William Miller, M.D.; Bone, Henry Mankin, M.D.; Bone Marrow, Patrick Beatty, M.D.; Cornea, Peter Laibson, M.D.; Skin, Irving Feller, M.D.] Perhaps even more exciting than what has already been accomplished by transplantation is the obvious scientific and technological momentum that will undoubtedly expand our medical horizons even further in the future.

But now the dilemma—efforts at acquiring, financing and equitably distributing precious transplantable resources—in other words realizing our full potential—are not, at the present time, providing everyone in need with the opportunity to benefit by this approach. As you know, our ability to sustain life, alleviate suffering and address disease by transplantation will get even better in the future, and it is our collective conscience, wit and wisdom that must minimize, if not eliminate, the tragic circumstances of current and projected unmet needs. The cornerstone of clinical transplantation is medical science and the building blocks are an adequate supply of satisfactory organs and tissues, appropriate medical facilities, proper numbers and types of trained professional personnel, an ongoing program of research and education and mechanisms to pay for all of this. The mortar is a strong recognition, desire and mandate from the public to put this type of program together and support it.

The proverbial glass is, in my estimation, half full—not half empty. There are many programs currently in place to enhance public and professional awareness, identify potential donors, recover desired organs and tissues, match these to waiting recipients and accomplish transplant procedures. In fact, these efforts have provided approximately 5,500 kidneys for transplantation in the United States in 1983, more than 70,000 since this program began; over 800 heart, 500 liver and 300 pancreas transplants have been carried out since these approaches were initiated and between 15,000 and 18,000 corneas were donated and transplanted last year alone. A growing percentage of the 100,000 to 200,000 bone grafts accomplished annually in the United States represent donated, banked tissues and thousands of skin grafts required for burn victims were made available. A more advanced version of this "system" has provided us with millions of units of the highest quality blood the Nation has ever had available, and done so through a totally non-profit and almost completely voluntary system of donation without financial compensation to the donor.

This clearly represents a commendable effort, and the praise belongs to many of the individuals and organizations represented here today; but these accomplishments have not been sufficient. It remains an uncontested fact that many individuals in need of transplants still face obstacles before being given the opportunity to benefit from the current state of medical expertise. Some of these issues will be more fully explored this afternoon and are represented by title in your program. The list is not meant to be inclusive or prioritized, merely a start. [Committee on Patient and Family Issues, Amy Peele, R.N.; Committee on National Networks, William Braun, M.D.; Sale of Organs—State Legislative Activities, Richard Merritt, M.A.; Multi-Organ Transplants—Report of An N.I.H. Conference, Nicholas Feduska, M.D.; Public Education for Transplantation, Ira Greifer, M.D. and Jeffrey Prottas,

Ph.D.; Professional Education for Transplantation, H. Arnold Muller, M.D.] Parenthetically, I believe the discussions of "Patient and Family Issues" and "National Networks" represent tangible progress by ACT toward clarifying issues and exploring solutions.

Despite the attention of many devoted and effective professional societies educational and charitable foundations, public advocate groups, organ procurment agencies, medical centers, a vast array of health care professionals, insurance providers and concerned citizens, our current approach to organ and tissue donation suffers in several ways. These include some degree of fragmentation and duplication in efforts, orientation towards single organ and tissue interests, persistent unawareness by the public and many health care professionals as to the magnitude of the dilemma or knowledge of existing resources (which leads to their lack of involvement in pursuing solutions) and, finally, constraints must be recognized in the size of the potential donor pool. In theory, all these problems except the latter can be successfully resolved; and in the case of the donor pool, we can certainly increase the percentage of individual's agreeing to provide organs and tissues.

Co-ordinated communication and attention to these issues alone will greatly enhance the availability of transplantable organs and tissues. This, I believe, is the core about which the American Council on Transplantation is being built. The issues I have raised with respect to transplantation are no secret today, nor have they gone unrecognized by many other organizations and individuals in the past. Indeed, initiatives directed towards improving these circumstances have come forward from many directions, and as a public we must recognize and be appreciative of these efforts.

With specific reference to the American Council on Transplantation, we must recognize the concern and action demonstrated by Dr. C. Everett Koop, Surgeon General of the U.S. Public Health Service. His personal involvement in this area lead to a meeting at Project Hope of the Steering Committee that was to initiate the American Council on Transplantation. This conference was attended by over 40 individuals representing a vast array of interests and expertise in the field of transplantation, including representatives of the American Association of Tissue Banks, the American Society of Transplant Surgeons, the American Academy of Pediatrics, the American and National Medical Associations, the American College of Emergency Physicians, the American Hospital Association, the North American Transplant Coordinators Organization, the American Association of Critical Care Nursing, the American Nurses Association, the National Kidney Foundation, the American Liver Foundation and Children's Liver Foundation, bioethics groups, organ procurement agencies, eye banks, blood services, insurance carriers, the federal government and many others.

The gathering was catalyzed by the Surgeon General, following which the group reached a consensus on the need to establish an independent federation of professional peer groups with expertise in tissue and organ transplantation. Here I wish to stress the concept of an independent federation, a point I will return to again before concluding. The group was well aware of the need for speedy action, given the urgency and gravity of many issues before them (and now "us"). Accordingly, general goals were established, a name for the federation was chosen, interim officers were nominated and elected and dates for the first Annual meeting were determined.

Let me recite for you the general goals adopted at that meeting: 1. to motivate the public to donate organs and tissues for transplantation; 2. to encourage health care professionals to identify and refer potential donors to organ recovery programs and tissue banks; 3. promote equitable access and effective use of multiple organs and tissues and 4. address the technical, ethical and financial issues involved in organ recovery and transplantation. These goals are broad and noble, and it was not at all difficult for those people attending the conference to embrace them enthusiastically.

It was my personal perception as well as that of many I have spoken with that ACT would represent the sum total of our best efforts by creating a cohesive national framework in which established and independent groups could collaborate with direction, flexibility, co-operation and innovation. In concept, ACT will take a good system and make it better. Advantages of this federated approach include the fact much of the system already exists and is in place. A careful analysis of the present transplant effort will permit an organization such as ACT to encourage, promote and expand the effective elements of the current system as well as identify and address inadequacies in ways deemed appropriate by its membership. As a federation, the Council will combine the currently fragmented resources in such a fashion as to provide a more effective impact in areas of education, training, organ and tissue recovery, banking and most equitable distribution, as well as suggest mechanisms

compatible with appropriate funding for transplantation. A similar approach provided highly successful for the American Blood Commission over 10 years ago.

Since late September, the interim officers have applied themselves to the charge provided them by the Steering Committee. That was to establish the Council as a real and visible organization, with an internal structure capable of generating a national framework in which members could identify issues pertinent to successful organ and tissue transplantation programs, address these in meaningful ways and, finally, to organize the first annual meeting of the Council that was to occur on this particular date.

Now comes my favorite part of this address, the opportunity to recount what we have done and to thank the many people who have assisted our independent efforts. In November 1983, ACT established an office at 1825 I Street in Washington with a full-time administrative staff. The first three months rent has been donated by our landlord, Business Resources Corporation. Legal counsel has been provided by the firm of Beveridge and Diamond (particularly J. Marshall Coleman and Virginia Albrecht), accounting services by Coopers and Lybrand (particularly A. Michael Quint) and assistance with public relations by the firm Hill and Knowlton (particularly Mark Grayson and Nancy Glick). All these services have been received on an pro bono basis during our organizational phase so that no loss of momentum would be incurred. Subsequently, articles of incorporation were filed, our tax-exempt status application submitted and by-laws established that will permit the Council to move ahead with the same enthusiasm that characterized our other initial steps. The American Hospital Association donated sufficient funds to temporarily support an interim executive director, Dr. Benjamin Baker, who has approached his short-term commitment (ending in March, 1984) with the zeal and brilliance that marked his career as a former Deputy Assistant Secretary for Defense and Deputy Surgeon General for the Air Force. Giving directions to a former two-star general fulfills one of my life's fantasies, but I have gotten more in return than I expected. As is often typical of Executive Directors, the full impact of their wisdom is rarely appreciated in full, but let me publicly assure you that he has been an indispensable element in our efforts to date and will be sorely missed in the near future.

Indeed, there have been many other contributors to our effort far to numerous to mention in detail here, but I must point out that the Department of Health and Human Services has provided the Council with seed funds totaling \$100,000 in a co-operative agreement, the only string attached being that we address the noble goals I stated previously. The private sector has also donated generously to ACT and numerous individuals and organizations have spontaneously contacted us with the desire to provide funds, services or personnel to help address our important and demanding mission. I would also like to thank all the members of the Council's Steering Committee, especially those actively serving as interim officers and committee chairpersons.

This brings me to a more sensitive portion of my address, that is explaining what ACT is not. First, ACT is not a substitute for any of the individual organizations that participate in our independent, federated efforts. Each organization has a strong tradition of their own excellence, independence, direction and agendas, and I expect them to continue vigorously with their own points of view. It is my hope that the federation will achieve an overwhelming consensus on a wide range of issues coming before the Council. Nonetheless, individual identity should not be lost, for this would weaken the basic concept of a federation. Please keep in mind that differences of opinion, perceived or real, can be healthy, especially when expressed and worked through with honesty and dedication to common goals.

I would submit we saw the potential merits of a federated approach demonstrated over the two days preceding this meeting. Again catalyzed by Dr. Koop, a symposium entitled "Maintenance of a Cadaver Donor for Multiple Organ Procurement" was organized under the auspices of the National Institutes of Health and co-chaired by Dr. Kenneth Sell, Scientific Director of the National Institute of Allergy and Infectious Disease and by Kenneth Goodman, Medical Services Liaison for the Upjohn Company. This very exciting initiative was not the sole focus or agenda of any specific group, but rather a successful amalgamation of multi-disciplinary expertise. As pointed out at the meeting, initiating directions are only a beginning, maintaining the dialogue and co-operation is the key to successfully and expeditiously resolving issues. I would submit that the American Council on Transplantation should provide for this type of ongoing relationship between very knowledgeable, competent and dedicated groups as exemplified by the NIH Symposium, those brought together in September at Project Hope and again here today.

Next on my list of what ACT is not, and contrary to some peoples' perception, the American Council on Transplantation does not offer itself as an alternative to any-

thing except the void created by the absence of an independent, altruistic national forum. To be blunt and specific, in the hopes of avoiding confusion and misconceptions in the future, ACT does not consider itself in competition with other initiatives that may have impact on transplantation, including pending legislation. By the same token, the issue of specific legislation has not been addressed within the framework of ACT to date, so the organization cannot be perceived as either supporting or rejecting legislative initiatives or any other agendas developed outside the Council. Since ACT is a federation, individual participating organizations may certainly be identified with their own points of view in these matters, and I can assure you honest differences of opinion exist.

To continue, ACT has not convened itself for political purposes. This misconception by some has caused me a great deal of difficulty and anguish, and I have felt considerable personal concern, with the only comfort being that the slings and arrows have come at me and the Council from both sides of the "political" fence. Perhaps that is the ultimate compliment, but it interferes and I wish it would stop. I am not, and ACT is not to be construed as a spokesperson for Congress, for the Administration or for any specific individual organization or interest group. Allegations to the contrary are difficult for me to accept. Not being totally naive, however, I do understand the background for some of these misconceptions, although they do not alter the reality of the situation. Let me also state that I do not feel that I or the Council will become a vehicle for a representative of an individual or organization just because they express pleasure with what ACT is or intends to accomplish. If judged by our actions, we may have been politicized by others but remain independent by deed. In fact, our only official posture as a Council (beyond our stated goals) has been to express concern over the proposed sale of organs, a statement adopted by the full Steering Committee in September. Consequently, I will continue to be grateful for credible support for ACT wherever it arises, but be assured it does not reflect negatively upon the independence or the governance of our organization. Perpetuating misconceptions in the future, unsubstantiated by deed, flagrantly interferes with ACT's efforts to raise and address issues important to further development and refinement of a fair, comprehensive and accessible national transplant program designed to serve the public.

Let me now turn specifically to what I see required for the future. ACT will gain its strength from broad-based and appropriate input provided by both organizations and individuals. I personally feel, and the Interim Executive Committee members present at our most recent meeting on January 9th unanimously concurred in the form of a motion, that the *governance* of the American Council on Transplantation must reside with professional organizations, but that both organizational and individual membership should be continued and encouraged.

The highly complex nature of transplant-related issues facing us demands the full weight and wisdom of knowledgeable professional groups, as partially represented by the original steering committee. The impact of these issues on society and on individuals, and the fact that many solutions and all the benefits will accrue to the public, demands that public input be recognized. I must hasten to add that ultimately we are all going to relate as individuals and those of us representing organizations are proudly and inescapably also individual members of the public. Consequently, it is the decision of the current ACT Executive Committee to ask the officers and members of the Board to be elected tomorrow to address as a priority issue the restructuring of the Council and its by-laws to reflect this needed direction. It is my great hope, that the wisdom of individuals voting tomorrow will be to vigorously support and, indeed, mandate the formation of an organization of organizations, but one clearly responsive to individual needs.

So there you have it, the good news and the bad, the challenge met and the challenge that persist. I believe it is time to identify and support, in unison, comprehensive and feasible approaches that have as their goals increased numbers of tissues and organs suitable for transplantation; appropriate facilities and personnel for implementing recovery, transplantation and equitable distribution of these precious resources; continuing support for basic research to insure an even brighter future and a system of financial support that the public as a whole, and as individuals, can afford—and not afford to be without. The direction I envision for the American Council on Transplantation places its faith firmly in professional organizations, with the collective wisdom and input of the public, to address and resolve many of our transplantation needs effectively, efficiently, quickly and with fiscal responsibility. As sensitive and concerned people, we are all saddened when our current approach to transplantation cannot provide all individuals and their families with the necessary resources, be they the organ itself, financing, scientific expertise or surgical facilities. We must, however, constantly know that we are putting forth our best

effort and strive to do even better in the future. From that perspective, we can all feel proud and move ahead, with tangible progress serving as the yardstick for measuring our efforts. Remember, you can't transplant rhetoric. Thank you.

[Attachment]

AMERICAN COUNCIL ON TRANSPLANTATION—INFORMATION SHEET

Significant advances in transplantation technology have occurred over the past several years. Further improvements in the scope and effectiveness of these procedures can be anticipated as yesterday's impossibility becomes today's challenge and tomorrow's achievement. That technology now offers hope on an ever-increasing scale. It now includes skin, eye, kidney, heart, lung, pancreas, liver, and blood. As a result, the requirement for appropriate organs and tissues crucial to transplantation has increased beyond the ability of existing individual organizations to fully satisfy. This problem has brought into sharp focus the need for a more coordinated national approach to organ recovery and donation.

Interested panels of experts convened during 1983 to address the entire range of transplant needs for both children and adults. Their task was to define the issues, discuss possible solutions, and propose effective strategies. Their premise was that the present voluntary system of organ and tissue donation is a satisfactory framework upon which we can build a more effective national resource. Participants were a crosssection of individuals and organizations representative of all facets of transplantation.

The result has been the formation of the American Council on Transplantation (ACT). ACT is an independent federation of individuals and organizations concerned with the donation, equitable distribution, and transplantation of organs and tissues. Its members recognize that they share common goals, and will be strengthened if they unite their energies for these goals. Accordingly, ACT proposes to:

- Motivate the public to donate organs and tissues for transplantation;
- Encourage health professionals to identify donors and refer them to organ procurement programs and tissue banks;
- Promote equitable access to and effective use of multiple organs and tissues; and
- Address the technical, ethical, and financial issues involved in organ recovery and in transplantation.

ACT's initial agenda will include efforts to:

I. Educate the public

Coordinate a mass media information resource focusing on the scope and success of current transplantation efforts and emphasizing the need for increased donations of organs and tissues;

Develop programs to assist patients and their families in issues associated with transplantation: financial, logistical, organ or tissue acquisition, and other supportive needs; and

Provide a forum for considering the ethical questions posed by transplantation.

II. Educate health professionals

Develop education programs emphasizing the scope and success of current transplantation efforts and the need for increased donations of organs and tissues; and

Provide guidance and resources to encourage donor identification, referrals, and support for potential recipients and their families.

III. Enhance donor identification and referral

Encourage States and hospitals to develop clear policies and practices on determination of brain death;

Encourage hospitals to identify and utilize suitable organs and tissues in a timely fashion; and

Improve communication and cooperation between organ and tissue recovery programs, health professionals, and acute care hospitals.

IV. Encourage multiple organ and tissue availability

Promote uniform donor management procedures, including surgical recovery and preservation of organs and tissues; and

Develop improved mechanisms for distribution.

V. Collect data on organ and tissue recovery and transplantation

Encourage studies on topics such as: current and future needs for transplantation; attitudes, knowledge, and other concerns about donation and transplantation among health professionals, the general public, special population groups, and families.

VI. Assure equitable access

Explore ways to make organs available to transplant patients on an impartial basis.

ACT's interim executive officers are: President, *Gary E. Friedlaender*, M.D., Orthopedic Surgeon, Yale University School of Medicine, New Haven, Connecticut; Vice-President, *Oscar Salvatierra, Jr.*, M.D., Transplant Surgeon, University of California, San Francisco, California; Secretary, *William S. Kerr*, Director, University of California Hospitals and Clinics, San Francisco, California; Treasurer, *Amy S. Peele*, R.N., Senior Transplant Coordinator, Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois; and Member-at-Large, *Donald Denny*, Director of Organ procurement, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania.

ACT is open to membership from organizations, health professionals, and individuals interested in organ and tissue donation and transplantation. For further information, please write or call: American Council on Transplantation, 1825 I Street, N.W., Suite 400, Washington, D.C. 20006, (202) 429-2067.

BLUE CROSS AND BLUE SHIELD ASSOCIATION,
Washington, D.C., March 1, 1984.

HON. ANDREW JACOBS,
Committee on Ways and Means, Subcommittee on Health, U.S. House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: We would like to submit the enclosed statement to be included in the record of your February 9 hearing on the National Organ Transplant Act (H.R. 4080). Our views on H.R. 4080 can be summarized as follows:

1. We commend the purposes of H.R. 4080.
2. With respect to Title I of the bill, we question the appropriateness and practicality of the government taking such a pervasive role in organ procurement activities.
3. We generally support the concept found in Title II that Medicare reimbursement for transplants should be limited to a designated number of facilities.
4. We support the prohibition of the sale of any organs (Title III).

I would like to note that since H.R. 4080 was introduced, more individual Blue Cross and Blue Shield Plans have decided to cover various types of transplants. These decisions have sometimes evolved from a difficult mix of new and expanding technologies, political pressures and market demand rather than a thorough assessment of the costs and benefits and the appropriateness of the procedures. We feel that these recent realities only underscore the points raised in our testimony.

We would be pleased to be of assistance as you consider H.R. 4080.

Sincerely,

MARY NELL LEHNHARD, *Vice President.*

Enclosures.

STATEMENT OF THE BLUE CROSS AND BLUE SHIELD ASSOCIATION

The Blue Cross and Blue Shield Association, representing the nation's 99 Blue Cross and Blue Shield Plans, is pleased to present for the record this statement on H.R. 4080, The National Organ Transplant Act. The statement is divided into four major sections: the first three focus on issues specific to the three titles in the bill; the final section addresses the need for an autonomous, broad-based entity to support assessment of complex technology.

TITLE I

Under this Title, the federal government appears to be taking on a major new role. This bill would authorize a program of grants to develop and expand local organ procurement organizations throughout the nation. In addition, the bill requires the Secretary to establish a U.S. Transplantation Network which is to maintain a national registry of individuals who need organs and operate a national computer system and a 24-hour telephone service to facilitate the matching of donor organs with potential recipients. The proposed programs would cover all forms of organ transplants (e.g., skin and cornea transplants).

We applaud the intent of this bill. We question, however, the appropriateness and practicality of the federal government taking on such a pervasive and potentially intrusive role in organ procurement activities at a time when the private sector, in partnership with the federal government, is engaged in activity which holds much promise for addressing the very problems which this bill attempts to address.

Voluntary organizations have traditionally taken responsibility for procuring organs for transplantation. This is not to say that improvement in the coordination of these activities is not warranted. Clearly there are gaps in the current system, but we believe that the most appropriate response to the existing fragmentation is to coordinate the many activities of the private sector, not compete with them. In this regard, we are encouraged by the Administration's proposal to help support the American Council on Transplantation (ACT) which could provide a vehicle in the private sector for coordination of transplantation activities throughout the nation.

The overall goal of this umbrella organization is to develop better approaches for coordinating the organ procurement efforts in the private sector. The Council is to undertake a series of activities which should contribute substantially to increased availability of organs for transplantation. We are hopeful that through ACT and similar private sector activities, the necessary framework will be established to develop a more effective system of organ procurement while maintaining the flexibility and creativeness of local private sector initiatives.

Our first concern with a new federal program derives from the rather rigid and prescriptive rules it would require in order to carry out its mission. Such a prescriptive approach is clearly reflected in the provisions of the bill which specifically lay out not only the function, but the structure, of all organizations which would receive grants or contracts under the provisions of this bill.

In addition, we are concerned with the administrative feasibility of implementing a federally mandated national registry or a national network of local transplantation procurement programs which could possibly be responsible for all forms of organ transplants. We believe such a program is far broader than necessary. Several forms of transplants have become fairly common (e.g., skin, cornea) and may not warrant the national tracking required by this bill.

We further question the provision in Section 372 to support the U.S. Transplantation Network from the Medicare Hospital Trust Fund. If the Network is to serve the entire population, then it should be more broadly financed and not be funded through the trust fund which is already sorely pressed. If the Network is to serve only the Medicare population, we think it is ill-advised.

In summary, it is our opinion that private initiatives should be given a chance before we commit major public funds to activities which may be equally or better met through the private sector. If the private sector initiatives do not meet the need, and the federal government steps in, then the government grants and activities should focus on those areas of the country and those types of efficacious organ transplant procedures which have been shown to require more than the private sector efforts can supply. Except for the most unusual circumstances, the federal program should be a temporary intervention designed to stimulate or otherwise shore-up the private sector's capacities.

TITLE II

We wish to state our general support for the provisions in this title which would grant the Secretary the authority to restrict Medicare payment to services which are furnished at a limited number of designed centers.

Experience with cardiovascular surgery and other very complex procedures suggests that the medical centers with large volumes will have the best clinical results. The same experience also demonstrates that, if payment is assured, many centers with no prospect of large volumes will perform "prestigious" procedures. This experience leads us to feel that there is merit in the idea of contracting for transplant services with selected medical centers on the basis of experimental criteria. It could encourage the large caseloads for participating centers which seem to correlate with the best success rates, while achieving efficiencies likely to yield an optimum cost for each procedure. This concept fits well with our own efforts to be prudent buyers of health care for our accounts and subscribers.

While we are highly supportive of the objective of this Title, we do want to raise some concerns of a more technical nature. First, although we do not believe it is the Committee's intent, the language in Section 201 could be construed as requiring the Secretary to specify "medical criteria of general applicability" for all covered services. The Committee may want to clarify its intent by inserting "as he(she) deems appropriate" on page 13, line 14 after "the Secretary . . . may determine . . .". Related to that point, we would also note that the new authority granted the Secretary may be broader than intended. For example, the language on line 17, "person furnishing the services", could allow the Secretary to restrict performance of all surgical procedures to board certified surgeons. We would recommend limiting the new

authority to either "procedures which require extraordinary personnel and support facilities" or to certain types of transplants.

Our second technical concern is that the language on lines 16-20 of page 13 may not allow the Secretary to establish conditions of payment based on efficiency. For example, it is not clear that the language gives the Secretary the authority to selectively contract on a basis which includes efficiency criteria although that is clearly the intent of the Committee as demonstrated in lines 20-23. We believe inclusion of some type of efficiency criterion represents sound public policy, and urge any necessary clarification. If such a criterion is to be included, the Committee may want to consider limiting the Secretary's selective contracting authority to procedures which are not widely available, and which also require extraordinary personnel and support facilities. Otherwise, the Committee would be granting the Secretary authority to restrict payment to specified providers for commonly prescribed services and items such as physician services or durable medical equipment.

TITLE III

We support the provisions of this Title which prohibit the sale of any human organ.

NEED FOR AN INDEPENDENT ASSESSMENT ENTITY

Our experience has led us to conclude that there is an urgent need for the establishment of an independent, broad-based entity to support the evaluation of the extraordinarily complex new technologies which are rapidly coming to the fore. In this section we will review both our usual assessment process and the difficulties with this process which have led us to this conclusion.

Usual assessment process

The decision to pay or not to pay for a service depends upon contract provisions that specify the scope of benefits. Most contracts exclude payment for experimental/investigative procedures. The Blue Cross and Blue Shield Association's technology assessment process is geared to respond to the requirements of Plans administering those contracts. This requires the designation of procedures as either generally accepted medical practice or experimental/investigative. Such designations often change with time, as the application of procedures evolves.

The typical assessment process begins when a member Plan gets a claim for a procedure that is not already listed as either generally accepted medical practice or experimental/investigative. The Plan then either makes its own determination, using locally available advisory resources, or asks the Association to evaluate the new procedure. In either case, the determination often is made under the pressure of time, for there is an outstanding claim to be paid, or not paid, as the case may be.

We respond to such requests by accumulating published studies and other relevant information for presentation to a group of six physicians who constitute our Medical Advisory Committee. This Committee, and its parent Committee on Cost Containment and Professional and Provider Affairs, are charged with analyzing the data and making recommendations back to the Plan. The recommendations are then weighed by each Plan against the unique circumstances of its area.

In the typical assessment, the Committee analyzes the data to determine whether, and under what conditions, the new procedure results in predictable and desirable outcomes. That is, the analysis may show that the procedure can be used successfully when the diagnosis is x but not y. Thus, under specified circumstances, the procedure can be considered generally accepted medical practice. The skill of the practitioner in applying the procedure is not usually considered in these assessments.

During the process of our own technology assessments we maintain close communication with government activity. Agencies such as the Office of Technology Assessment, the National Center for Health Services Research, the Center for Disease Control and the Food and Drug Administration provide information and analysis. Staff from the Health Care Financing Administration frequently attend our meetings and participate in our discussions. In addition, the Association has built an information network with a number of medical specialty societies. Among these, the American College of Physicians and more recently the American Medical Association have established technology assessment programs that respond to inquiries from interested parties.

Difficulties with this process

The growing number of liver and other organ transplants and the concomitant increase in demand for coverage present Blue Cross and Blue Shield Plans with new

challenges. Liver transplants may currently be experimental or investigative when performed at most centers, but have arguably become accepted medical practice for certain diagnoses when performed at a select few. The varying ability and success of transplant teams and institutions reflect the early, developmental stages through which this new technology is growing. Some centers report consistently high and improving survival rates. Others appear unable to sustain equivalent success rates or to perform as well as the leading centers in their field. This variation from site to site complicates our traditional method of technology assessment. Liver transplantation, for example, seems to demand that the skills, resources and ability of the practitioners and their institutions be considered in the assessment process. The link between procedure and outcome, even for a narrowly specified set of diagnoses, is unusually dependent on the qualifications of the practitioners, and their institutional settings, and there are only a few practitioners and settings recognized as having the requisite qualifications.

Our traditional method of technology assessment has been severely strained by this new need to weigh the factor of practitioners skill and to recognize that the necessary skills are unevenly and sparsely available around the country. With the publicity attendant to these new procedures, and the paucity of institutions reporting high success rates, the nation is rapidly becoming a single medical community for purposes of organ transplantation. In our view, our ability to responsibly cope with such a situation in the future would be enhanced by two new developments: first, the effective performance of a broad-based, independent and dispassionate organization to assess these extremely complex technologies, including the issue of requisite practitioner skill and institutional support systems; and second, legally sound mechanisms for establishing payment practices such that they cover only necessary procedures for specified diagnoses for appropriate patients at qualified institutions.

The second item relates to the ability of the public and private sectors to reinforce each other in focusing resources in the most quality-enhancing and cost containing fashion. We are concerned over constraints on the private sector's ability to pursue just the kind of limited contracting here proposed for the Medicare program. Thoughtfully structured and implemented, our contracting with only a limited group of centers need not be an unreasonable restraint of trade. However, the risk of antitrust allegations by disgruntled providers is very real. We do not fear the outcome so much as the costs of the process. Antitrust defense is enormously debilitating. Related matters suspend indefinitely, as resources intended for the funding of patient care are diverted to litigation. This is a matter that we would commend to the Committee's attention. It is possible that some appropriate legislative safeguards against such legal challenges could be drafted.

Need for an independent assessment entity

To meet this need, we have supported the re-funding of the National Center for Health Care Technology. We have also helped to fund and have actively participated in the Institute of Medicine's effort to design a private/public sector entity to assess technology in medical care. A broadly-based mechanism, funded from multiple sources, may serve to accommodate a variety of needs for technology assessment. It could serve as an analytic clearinghouse for information on clinical trials or other clinical experiences, and could make recommendations on a procedure's efficacy, the circumstances of efficacy, or what future research may be necessary to establish these. We believe that government, as a major buyer of medical services, should be one of the participants in discussions on how best to handle transplantation, and that it is one of the appropriate funding sources for a neutral technology assessment entity.

Creation of such an entity would not only obviate the need for a National Center for Organ Transplantation, but would significantly improve the way in which we, as a society, deal with such issues. Had such an organization been in place ten years ago, it could have and should have, accumulated and evaluated the earliest information on organ transplants, identified prospectively what data should be captured to permit ongoing and consistent evaluation, and perhaps have established a research agenda to acquire additional critical information. Clearly, other technologies which are in their embryonic stages today will be confronting us in a few years with problems comparable to those now surrounding organ transplantation. The need is less for an entity focused upon a single technology than for a more versatile, continuing entity which can deal with the broad range of clinical development. Further, annual reports by such an organization, supported by both the public and the private sectors, would have a broader base of acceptance than a Secretarial report issued after consultation with the NIH Director and the FDA Commissioner.

SUMMARY

In summary, we commend the purposes of this bill, but question whether Title I of the legislation is needed at this time. The private sector has already demonstrated its ability to effectively handle many of the more common transplant procedures. However, there are many issues and concerns surrounding the less frequent transplant procedures. Clearly we need greater coordination of all our efforts. To this end, we are encouraged by the emerging efforts in the private sector to achieve greater coordination. We would prefer to see the results of these recent private sector initiatives before major government sponsored organizations are established. If these initiatives fail, government grants and other initiatives should be aimed at areas of unresolved needs as such areas are identified.

While we support the general thrust of the provisions included in Title II to provide the Secretary with authority to limit Medicare payments to designated centers, we have raised certain technical concerns with this Title.

We have mentioned our support of efforts to re-establish the National Center for Health Care Technology, and to aid and encourage the Institute of Medicine in this area. We hope that government, as a major purchaser of care, will participate with other interests in establishing improved, non-partisan means of evaluating both the status and the application of very sophisticated, very expensive technology. We would also support separate federal legislation to prohibit the sale of human organs.

STATEMENT OF PETER DOBROVITZ, ROCHESTER, N.Y.

Sirs, a year ago this month, I received what the Kidney Foundation calls "The Gift of Life." At the University of Pittsburgh Medical Center, I was the recipient of a kidney transplant after eight years of dependence on hemodialysis.

Today, my blood chemistry levels have gone from a constant state of near-toxicity to those of a normal healthy adult. The amount of blood present in my system has nearly doubled to normal levels. The onset of bone disease and decay that I was experiencing on dialysis has begun to reverse itself. The biochemical change has been nothing short of a miracle. My renewed outlook on life is a miracle. I am able to carry on my career as a television reporter with new enthusiasm. I have since married and look forward to a long and lasting relationship with my wife, Pat, who's been the inspiration for my recovery.

I say all this as a preface to my remarks concerning H.R. 4080, the bill now before you. On another occasion, I testified on the section of the bill dealing with the sale of donor organs, a practice that I find personally objectionable. Today, I wish to spend a few moments discussing the financial aspects of this legislation and why I believe it deserves your enthusiastic support.

There are two points that I want to address; the allocation of Federal funds for improving an organ procurement network and the approval of Federal funding assistance for the continued use of Cyclosporin A, the immunosuppressive drug that has revolutionized the kidney transplant procedure.

Every year, twenty thousand Americans are declared brain dead. Many do not wish to become organ donors or their families are opposed to the idea. It is the goal of the Kidney Foundation to change public attitudes in that regard. But, there is another nagging problem. It's a question of communication. I was lucky; the University of Pittsburgh is tied into an east coast organ network that allowed them to locate a donor kidney for me in Virginia and ship it within hours for transplantation.

Other kidney patients aren't as fortunate. Many times, valuable minutes are lost trying to locate available organs and perform the essential matchings needed to insure a safe transplant. The program proposed by this legislation can dramatically upgrade the system of communication nationwide and give more kidney patients the ability to rid themselves of dialysis. But, here is the bottom line; such improved success rates will also rid the Federal government of underwriting costly dialysis treatments!

That leads to my second point concerning Cyclosporin funding. It costs anywhere from \$30,000 to \$50,000 per year to maintain just one person on dialysis. In my case, that represents a Federal investment of nearly a quarter of a million dollars from 1976 through 1983! But Cyclosporin has changed all that. Its immunosuppressive qualities greatly lowered the chances that my donor kidney would reject. Without a related donor in my family, my chances for a successful transplant were 50-50. And of that, I had a 50-50 chance of a successful transplant without the side-effects and complications caused by other immunosuppressive drugs. That's a one in four chance of a transplant without risk. Not the best of odds.

With Cyclosporin, my success rate was 80 percent or higher. Now, a year after the transplant, I think it is safe to say that my odds for success were even better than that. And I have experienced absolutely no negative side-effects. I have noticed an increase in facial hair growth, but for 30 years I've always wanted a beard anyway!

Now, what does it take to keep my kidney functioning? Simply, one 350 mg dose of Cyclosporin liquid mixed with chocolate milk every morning and 15 mg of the steroid, Prednisone. As the kidney continues to function properly, those doses could be reduced to 100 mg and 10 mg, respectively. Currently, that dosage amounts to a little under two bottles of Cyclosporin a month; as little as one bottle every month and a half in the future. It's a quick and painless treatment, especially when compared to the 12+ hours a week I had to devote to dialysis. But there are problems ahead; serious financial problems not medical ones. Currently, I'm part of a University of Pittsburgh study group in conjunction with Sandoz Pharmaceuticals, the drug's manufacturer under the brand name, Sandimmune. I have been given my last free supply of the drug, which should last six months. But, unless the Federal government acts, I will have to begin purchasing the drug on my own. That's with an estimated price of \$140 to \$160 per bottle. That amounts to more than \$4,000 a year out of pocket, just to keep my kidney functioning. The financial strain is steep and that much greater for those on fixed incomes. That is why I strongly urge your support of the funding of Cyclosporin. Not from a humanitarian standpoint, but rather from your appreciation of the "bottom line."

Without Cyclosporin, the Federal government would be spending \$30,000 a year on me for maintenance dialysis. With it, the investment in my health could be cut by \$27,000 per year. That's per year . . . per patient. And with the knowledge of federal support, I'm sure more and more dialysis patients would turn to transplantation, thus dramatically reducing the number of patients on dialysis nationwide. I'm sure you can begin to see the dramatic reduction in Federal renal failure expenses. Cyclosporin funding, in time, would more than cover the cost of the communication network, as proposed by H.R. 4080.

And so, we have come full circle. Yes, you would be asked to spend large sums of money initially. You will be underwriting the use of a revolutionary drug for hundreds, and soon, thousands of kidney patients across America. That's the short term. In the long run, you will be freeing thousands more kidney patients from the rigors of dialysis and more importantly, from your standpoint, you'll be freeing the Federal government from a huge chunk of one of its most costly ongoing health care obligations. I know I speak with the voice of every transplant patient in America whose received the gift of life with the aid of Cyclosporin. We're counting on you to keep our lifeline flowing.

Just remember my history. Eight years on dialysis, \$250,000.00! Cyclosporin would not cost the government that much should I live for seventy more years!

Before I conclude, I have one more remark for the record. I wish to thank Hon. Barber Conable for giving me the opportunity to air my views. I've covered him for nearly ten years on Rochester television and have always found him to be highly professional, thorough and a credit to his party and office. Now, as a constituent urging support of this legislation, I found him to be eager, enthusiastic, responsive and impressively well-informed on this critical health issue. (And they say his forte is the Federal tax law!) In the past few days, the leaders of this government have all expressed their admiration for his work and the sense of loss caused by his decision to step aside at the end of this, his 10th term. I can only echo those sentiments and thank him sincerely for his efforts on behalf of this legislation.

EYE BANK ASSOCIATION OF AMERICA, SOUTHEAST REGION,
 Atlanta, Ga., February 7, 1984.

Hon. DAN ROSTENKOWSKI,
 Chairman, House Ways and Means Committee,
 Washington, D.C.

DEAR CHAIRMAN ROSTENKOWSKI: I would like to voice concern regarding HR 4080 by Representative Gore.

While I wholeheartedly agree with efforts being made to prevent the purchase of donor organs/tissue, I believe that passage of this bill would have a detrimental effect on established eye tissue programs.

As a volunteer involved for more than twenty years in the procurement of corneal tissue for transplantation, I sincerely feel that the success of eye banking is due to the efforts of individuals who have gained expertise in the specialized area of eye tissue procurement and transplantation as well as the assistance derived from rela-

tionships that have been developed with the medical people and other professionals involved in the team efforts necessary at our respective eye banks.

It has been my privilege to serve as Chairman of the Board of Trustees at the Georgia Lions Eye Bank, Inc. at Emory University where I have seen much progress made during recent years. From 25 transplants during 1973, our Eye Bank alone provided tissue for 1050 transplants in 1983, and in over 95 percent of the cases the surgery has been successful.

Although the single most dramatic use for eye tissue is the corneal transplant, research has taken on a high priority. Eye tissue not viable for transplantation is utilized in research programs where certain variables or abnormalities in the eye can give researchers new insight and provide a wealth of knowledge into causes and effects of specific phenomenon.

I sincerely believe that passage of the above bill would have an adverse effect on the future success of our eye bank programs and that increased cooperative efforts between organizations currently in place can accomplish the functions called for in Section 372, Title I, "United States Transplantation Network." It is felt that the bulk of this bill is unwarranted and would be counterproductive with our efforts. Thank you for your consideration of expressing opposition to this bill.

Sincerely,

Y. T. ABERNATHY, *President.*

STATEMENT OF MARY JANE O'NEILL, EXECUTIVE DIRECTOR, THE EYE-BANK FOR SIGHT RESTORATION, INC., NEW YORK, N.Y.

The National Organ Transplant Act contains a number of provisions that could seriously jeopardize the large network of eye banks that has been increasingly successful in providing corneal tissue for sight-saving transplants to thousands of patients each year.

As presently written, the bill gives priority, precedence and funding to kidney retrieval units. In the long run, this could mean that long-established eye banks would be eliminated, since federal funding would appear to be limited to organizations being reimbursed under Medicare for kidney procurement.

Additionally, and even more importantly, the bill seems to imply that a computerized network of donors and recipients will somehow solve the problem of shortage. You can have a million potential donors on file and ~~unless there is some system set up to identify those donors at death, the donation will not be made.~~ We need constant publicity to educate the public and we need workable systems in hospitals to make sure next of kin are asked about organ donation whenever a patient dies.

While the prohibition of organ purchases is most commendable, that section should include processing, preservation and quality control procedures among the reasonable costs not included in the term "valuable consideration."

Finally, I believe a much stronger effort should be made to coordinate the many private sector efforts before the Federal Government launches what could become a duplicatory and prohibitively expensive program of its own.

THE JOHNS HOPKINS ONCOLOGY CENTER,
OFFICE OF THE DIRECTOR,
Baltimore, Md., February 24, 1984.

Mr. JOHN J. SALMON,
Chief Counsel, Committee on Ways and Means,
U.S. House of Representatives, Washington, D.C.

DEAR SIR: May I refer to the National Organ Transplant Act, H.R. 4080.

We believe that the purposes of this legislation are laudable. It will be especially helpful to have a network which will facilitate the prompt distribution of organs to patients in desperate need.

I write to recommend that bone marrow (the organ that makes blood cells) be listed amongst the "human organs" (Sec. 373(e)(2) and Sec. 301(c)(1)).

Suitable family donors are not always available for patients with life-limiting aplastic anemia and related severe marrow failure diseases. Life-saving bone marrow may be obtained from healthy donors without significant risk of morbidity or mortality. A national registry of tissue typed donors and a distribution network would aid immeasurably in treating afflicted individuals effectively.

At our Center, we perform more than 100 bone marrow transplantations each year. We would be pleased to furnish expert testimony from Dr. George W. Santos,

a nationally recognized leader in the field of marrow transplantation, and others if it would be useful to your deliberations.

Sincerely,

ALBERT H. OWENS, Jr., M.D., *Director.*

THE JOHNS HOPKINS ONCOLOGY CENTER,
HEMAPHERESIS TREATMENT CENTER,
Baltimore, Md., February 24, 1984.

MR. JOHN J. SALMON,
Chief Counsel, Committee on Ways and Means, U.S. House of Representatives, Washington, D.C.

DEAR MR. SALMON: I have had the opportunity to read H.R. 4080: The National Organ Transplant Act. I congratulate the committee on its efforts to facilitate organ distribution and to remove the process from the commercial market place.

Inadvertently, however, you have excluded an entire type of human organ transplant; namely bone marrow transplantation. Since the first report of successful transplantation of human marrow in the late sixties, several thousand transplants have been performed in the United States.

Bone marrow transplants are performed in three types of disease:

- (a) Conditions of acquired marrow failure such as aplastic anemia.
- (b) Conditions where inherited defects can be corrected by marrow cells such as severe combined immune deficiencies, thalassemia major and perhaps someday sickle cell anemia.
- (c) Following intensive drug or radiation treatment of cancer. Bone marrow transplantation can result in a cure in acute leukemia, chronic myelocytic leukemia and lymphoma.

Today, bone marrow transplant is largely limited to patients who have an HLA identical brother or sister. This is due to the fact that there is no national system to find donors with the appropriate tissue type. Today there are over 100,000 blood donors who have been tissue typed and could be marrow donors. This has lead to many tragic situations: one patient in New York offered several thousand dollars for anyone who would be his donor. Another patient in the Midwest went to court to obtain the name of a blood donor who matched him. I think this is just the type of situation the National Organ Transplant Act is designed to avoid.

At this time several organizations including the Aplastic Anemia Foundation of America are starting to develop matching programs to identify marrow donors for patients without matched siblings. Fiscal support such as envisioned in H.R. 4080 would greatly accelerate this process and remove marrow donation from commercialism.

I respectfully request that H.R. 4080 be amended to include bone marrow donors: Page 10 lines 16-19 and page 17 lines 10-14 should be changed to read:

"The term 'organ' means the human kidney, liver, heart, lung, pancreas, bone marrow and any other human organ or tissue (including corneas, bone, and skin) included by the Secretary by regulation."

I hope you can be of assistance in this matter lest procurement of human marrow for transplantation be allowed to be the subject of barter in the market place. If I can be of any assistance to you in this matter please do not hesitate to ask.

Sincerely,

HAYDEN G. BRAINE, M.D., *Director.*

JUVENILE DIABETES FOUNDATION INTERNATIONAL,
New York, N.Y., February 6, 1984.

HON. ANDREW JACOBS,
U.S. House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN JACOBS: The Juvenile Diabetes Foundation (JDF) is an international voluntary health organization dedicated to supporting and furthering research and education in diabetes. We would like to express our strong support for, and urge that you report out, H.R. 4080, "The National Organ Transplant Act," as approved by the House Energy and Commerce Committee on November 18.

We support the various provisions included in H.R. 4080 pertaining to (1) the establishment of a grant program for the development of local organ procurement organizations; (2) the creation of a United States Transplantation Network; and (3) the establishment of an office within the Public Health Service (PHS) that would serve

as the Federal focal point for all organ donation and transplantation activities, public and private, throughout the United States. Furthermore, we believe that Congress should seriously consider providing reimbursement for organ transplantation procedures under the Medicare and Medicaid programs, an endeavor which would encourage private insurers to do the same. Finally, we are pleased that the bill prohibits the sale of human organs.

We would like to comment on several specific aspects of the transplantation issue that pertain to diabetes—kidney, islet cell, and pancreatic transplantations. While kidney transplantation is important to those diabetics who have suffered kidney failure, this is but one approach to treating one of the many complications of diabetes. Recent research breakthroughs in islet cell and pancreatic transplantation are exciting because they embody the potential to cure diabetes.

KIDNEY TRANSPLANTATION

It has been estimated by the American Society of Transplant Surgeons that as many as fifty percent of individuals with Type I juvenile onset diabetes develop uremia (kidney failure) from diabetic nephropathy (infections, hardening of the small kidney arteries, and damage to the filtering apparatus of the kidneys as a result of diabetes).

The two possible approaches to dealing with kidney failure are kidney dialysis and kidney transplantation. There are various ways a diabetic can receive kidney dialysis—in a hospital, a free-standing clinic or in the home. However, dialysis is a very expensive and time-consuming procedure. Costs for chronic center-based dialysis, not including costs for hospitalization for associated illnesses, are estimated to exceed \$25,000 every year an individual remains on dialysis. When hospital costs are factored in, the yearly costs of dialysis for a child can exceed \$70,000 per year. These costs are all reimbursable through the Medicare program.

On the other hand, the average cost of a renal transplant in the first year is approximately \$25,000–\$35,000. This figure decreases significantly in subsequent years to a minimal maintenance cost for medication. The medical costs of transplantation procedures are expected to decline as technology improves and as new and better immunosuppressive drugs are developed. Transplantation also allows the individual to return to a more productive life.

Furthermore, the diabetic receiving kidney transplantation exceeds the survival rate of the diabetic maintained solely on dialysis. There are about 5,000 kidney transplants performed in the U.S. every year and the technology is rapidly improving. According to Dr. Eli A. Friedman, Chief of the Renal Diseases Division at Downstate Medical Center in Brooklyn, New York "at least two out of three diabetic kidney recipients will be alive and will have functioning kidneys at least three years after surgery." Dr. Friedman reports that an increasing number of kidney recipients have lived beyond ten years and a few have passed the sixteen-year mark. As technology advances and as the drug cyclosporine, with its anti-rejection qualities, becomes more widely available the number of kidney transplantations will increase significantly, embodying the potential to greatly improve the quality of life of the diabetic.

BETA CELL TRANSPLANTATION

As mentioned above, we are excited about the prospects for islet cell and pancreatic transplantation. A normally functioning pancreas automatically provides necessary amounts of insulin to the system. The insulin-dependent diabetic must perform himself the function of a pancreas by monitoring blood-sugar levels and injecting proper amounts of insulin into the system at the proper times.

An exciting area of diabetes research—and one which embodies the potential to dramatically improve the quality of life of the diabetic within the next couple of years—is pancreatic islet cell transplantation. The islets of Langerhans contain the pancreas gland's insulin-producing beta cells. The successful transplantation of these cells into the diabetic may actually reverse diabetes in the body receiving the transplantation.

Dr. Paul E. Lacey and his team of researchers at the Washington School of Medicine two years ago successfully transplanted clusters of the insulin-producing cells from one animal species to another. Moreover, beta cells from the healthy rats transplanted into diabetic mice actually reversed the diabetes in the mice. At a recent meeting of the National Diabetes Advisory Board, Dr. Lacey stated: "Studies in rats have shown that isografts of islets will prevent, reverse, or arrest complications of diabetes involving the eyes, the kidneys, and the autonomic nervous system of diabetic recipients."

Initially, rejection of islet cells was a problem; however, seven different methods have been developed which will prevent rejection of isolated adult islets transplanted between different strains of animals and different species. A second major stumbling block, the lack of techniques for the mass isolation of islets from large animals and man, has also been overcome. Finally, new methods are being developed for the purification of islet tissue.

PANCREATIC TRANSPLANTATION

Ongoing studies in the area of pancreatic transplantation focus on procurement of pancreas organs, new drugs to halt rejection, and transplantation techniques. All of these areas require further investigation. Dr. David Sutherland of the University of Minnesota Medical School, a pioneer in the field of pancreas transplants, has indicated that the potential for application of pancreas transplantation "probably exceeds that of the liver and may approach that of the kidney." As transplant technology improves in other organ transplant procedures, and with the introduction of cyclosporine, improved results with pancreatic transplants can be expected.

RECOMMENDATIONS

JDF is extremely excited about all of these promising areas and we are pleased to see national attention being focused on the entire issue of transplantation. As noted above, we support H.R. 4080. We would respectfully recommend that:

1. In establishing a U.S. Transplantation Network for matching donors with organs, the future need for pancreas glands for diabetics should not be overlooked.
2. The transplantation office created by the Secretary within PHS should devote some of its resources to kidney transplantation for diabetics and to the emerging opportunities embodied in islet cell and pancreatic transplantations.
3. The transplantation task force should have representation from the diabetes community.
4. Funding for research and clinical trials for islet cell transplantation should be substantially increased because of their potential to provide a cure for diabetes.

We thank you for this opportunity to comment on this important legislation. The world is thrilled with the progress made in kidney, liver, and heart transplantation. It is imperative that neither Congress, NIH, the new entities charged with coordinating transplantation efforts, nor the public lose sight of the great potential which transplantation technology offers the nation's 1.5 million insulin-dependent diabetics.

Sincerely,

JASON S. ROBERTS, *President.*

STATEMENT OF NATIONAL ASSOCIATION OF PATIENTS ON HEMODIALYSIS AND TRANSPLANTATION, INC.

The National Association of Patients on Hemodialysis and Transplantation, Inc., more frequently known as NAPHT, is pleased to submit comments for the record on House Resolution 4080, the National Organ Transplant Act.

NAPHT is an association of kidney patients with over 11,000 members from all U.S. states and territories. Our members include patients who are treated for irreversible kidney failure with every available modality, including kidney transplantation, both from living-related and cadaveric donors. The topic of improved organ procurement and transplantation is of great concern to us.

Before addressing the specific issues in H.R. 4080, we would like to make a few comments about organ transplantation. NAPHT does not endorse any one medical therapy as being preferable to other available therapies. We believe that patients should have the choice of all available therapies and that reimbursement policy should be as neutral as possible vis-a-vis currently available therapies. Patients should be encouraged to choose the option that is best suited for them.

Organ transplantation has received a great deal of media and Congressional attention over the past year. It is being painted as the ultimate therapy, whose time has come with the advent of Cyclosporine. While most kidney patients see transplantation as the ultimate solution to the problem of kidney failure, many feel that a transplant is not yet the right choice for them.

First of all, for many people life is not as bleak on dialysis as the media would lead us to believe. Many of our members have adjusted well to dialysis, and they are not yet willing to risk a transplant. The side effects of immunosuppressives, including Cyclosporine, can be devastating and even fatal. Although the success rates for

transplants have continued to improve, an unsuccessful transplant is still a distinct possibility. Other of our members, of course, are eagerly awaiting a transplant, and we believe that a transplant should be available to them.

NAPHT favors policies which remove barriers to kidney transplantation. However, we view with a great deal of concern undue pressure on kidney patients to receive a transplant. Suggestions that Medicare coverage might be limited for those individuals who did not choose a transplant, if the transplant surgeons felt the patients were medically suitable for a transplant, are viewed with great alarm by our organization. We urge Congress to continue to endorse policies which allow medical decisions to be made by patients and physicians, rather than by reimbursement policy.

ORGAN PROCUREMENT IMPROVEMENT

NAPHT is pleased with the interest of Congress in improving the organ procurement system. We are concerned, however, that the effort to improve the system not interfere with successful organ procurement activities already underway. There is clearly room for improving the system, particularly through education of health care professionals. Progress made to date, however, must be recognized and preserved.

There are a number of ethical, medical, and educational issues which need to be addressed in the effort to increase the supply of organs for transplantation. The task force on organ transplantation that would be established with the enactment of the National Organ Transplant Act is obviously one forum for addressing these specific issues. We are concerned that no members from the patient population are included on this task force. Three members of the general public are included. We urge that an additional three members be added to the task force who are either patients or family members of patients, who need or have had an organ transplant. We believe that patients can bring a valuable perspective to this task force.

SALE OF ORGANS

NAPHT is opposed to the commercial sale of human organs for transplantation, and we are pleased that this legislation would make such sale illegal. Our opposition is based on several basic concerns. The first concern is that the sale of organs raises ethical problems. Kidney failure strikes persons in all walks of life, although its occurrence is more frequent per capita among Blacks than Whites, primarily due to higher instances of high blood pressure among Blacks. If purchasing an organ over became the primary means of obtaining a transplant, those of greater wealth would obviously be at a substantial advantage. We have lived through the days of selection for treatment prior to the enactment of H.R. 1 in 1972 and find any return to that type of selection process, which invariably favors Whites over Blacks and the wealthy over the poor, to be repugnant and morally reprehensible.

In addition to the question of fairness of the sale of organs, we can not help but feel that allowing such sale would actually decrease the number and quality of organs available for transportation. If the public perceives the problem of organ donation to have been resolved through the sale of organs, would not the voluntary donation of organs for transplantation decrease? Would there not be an incentive also for family members to fail to disclose all parts of the medical history? The experience with paid blood rather than voluntarily donated blood with its eight times greater risk of post-transfusion hepatitis should be noted in this regard.

In addition to the fact that the sale of organs would create major ethical and practical problems, we see no need to initiate such a system. With better education of health care professionals and a better retrieval system, there should be sufficient cadaveric organs available to meet the need for kidneys for this country. The estimates of at least 20,000 suitable donors for organs each year suggest that there is no need for commerce in human organs.

NAPHT is concerned, however, that there be no prohibition against reimbursing living organ donors for their out-of-pocket expenses, including lost wages, since they often incur substantial expenses when donating a kidney.

IMMUNOSUPPRESSIVE COVERAGE

We are pleased with the provision of H.R. 4080 which would extend Medicare coverage to immunosuppressive drugs. Conventional immunosuppressive drugs are expensive and cause a financial burden on some patients. Cyclosporine greatly increases that financial burden. We do not believe that lack of coverage has kept anyone from receiving a transplant in the past. However, we are aware of patients

who have lost a functioning transplant because they decreased the dosage of their immunosuppressives below therapeutic levels or quit taking them altogether because of the costs. In either case, the resulting organ rejection and subsequent return to dialysis is both expensive to the government as well as devastating to the patient. With the greater cost of Cyclosporine over conventional immunosuppression, we can only believe that this type of unfortunate result will increase. We have already had conversations with a number of patients who began Cyclosporine when it was still an experimental drug (and therefore were not charged for it) who are now considering to stop taking the medication if financial assistance does not become available. We have also been advised by transplant surgeons that they are beginning to utilize a means test prior to transplanation because of the cost of Cyclosporine. This is a most unfortunate occurrence.

We again thank the Committee for its interest in improving the organ procurement system and dealing with major issues surrounding organ transplantation. We are willing and anxious to work with those who are seeking to improve life for kidney patients as well as for other individuals in need of organ transplantation.

STATEMENT OF WILLIS B. GOLDBECK, PRESIDENT, WASHINGTON BUSINESS GROUP ON HEALTH

My name is Willis Goldbeck, President of the Washington Business Group on Health. As an organization of the nation's largest employers, we share with the Congress a deepening concern for the seemingly relentless escalation of medical care costs. To the extent that these costs are the result of waste, fraud, the neglect of prevention, the absence of market forces, and frequently misguided utilization by an uninformed public, the solutions are many and obvious, albeit complex and difficult. However, there are other forces stimulating the escalation: an aging population and the advance of technology, which lend themselves more to ethical debate than to economic and political solutions.

Today's issue, organ transplants, falls into the latter category. We have accepted your invitation to present testimony for two reasons:

One, we believe the largest purchasers of medical care must be party to the political and economic processes of rationing.

Two, corporations are actually nothing more than aggregations of individuals—people and their families who share with the rest of society the fears of dying, hopes for medical miracles, concerns for costs, and uncertainty about potential solutions.

The temptation to duck this issue is overcome by the emotional and ethical depth it evokes in each of us, and thus in our institutions. There is no long developed, erudite, much less unanimous, "business voice" on this issue. The articulation of our current views and concerns may be less than cohesive and subject to change over time, but that is excusable. To be silent, however, would be inexcusable.

The way we integrate our biomedical, technological riches with our limited resources to serve the quality of life and dignity of death that ultimately defines our individual human passage will be a great test of our society and its leaders.

Today's issue is of no less magnitude. It is a surrogate for the more global ethical deliberation that cannot become law, nor suits the rigors of regulation, nor submits easily to the brevity inherent in our political timetable.

The authors and co-sponsors of H.R. 4080 deserve praise for forcing Congress and the rest of us to squarely face these issues. In the long run, the mere process of these deliberations may be more significant than the proposed legislation itself.

There are several elements of H.R. 4080 that are justifiably controversial. One, however, deserves unequivocal support: Title III—Prohibition of Organ Purchases.

In this era of appropriate concern for excessive governmental interference and support for procompetitive strategies, we must not lose sight of the legitimate functions of government. Just as basic economic policy, civil rights, environmental policy, and defense are recognized as appropriate for the guidance and constraints of legislation, so too must we use the power and principles of government to guarantee our citizens that there will be no market for body parts in the U.S.A. Quite apart from the moral issue, on a practical level the sale of organs will threaten the voluntary donor system now in place and which H.R. 4080 would strengthen.

Title I seeks to establish an organ procurement system that meets a well documented need. It would avoid all the negative aspects of profiteering. This system is consistent in purpose with the recommendations of the working group of experts convened by the Surgeon General in 1983. A few specific points need to be made:

1. The professional and public education goals are so important that they warrant specific funding. With minimal authorization levels, it is easy to anticipate that

these vital functions will be given low priority. Congress can avoid this, and help meet its overall goal, by establishing that a specific percentage of the authorization be used for education. Based on the polls presented at the 1983 hearings, the public is both aware of and supportive of transplantation. The need is to change behavior, especially that of families and medical professionals.

2. The Board of Directors criteria should be expanded to include representation from employers and/or unions. As in virtually all other health institutions today, the voice of the purchaser is needed. Further, the workplace sector represents the best, largest, and most organized locus for dissemination of the educational information required under this bill.

3. As written, there will be too many centers. Neither real needs nor the resources to be made available by this legislation suggest than an unlimited (except by the restrictions on duplication of service areas) number of centers should be supported. States and other normal geopolitical boundaries do not suit this purpose. It is, therefore, recommended that the legislation fund a restricted number of selected centers and expand that number as experience, need, and resources dictate.

4. Section 371(b)(2)(5) requires an annual evaluation of each center, by each center. We agree with the need for evaluation but would urge you to consider funding independent evaluations based upon standard criteria established through NIH or perhaps the Institute of Medicine.

5. The Transplantation Network and Scientific Registry are needed even if the rest of the legislation were not to become law. The time to establish the data base and collection/distribution systems is now, prior to supply and demand pressures of untold emotional and financial magnitude. These systems should be designed to facilitate, not replace, the Uniform Anatomical Gift Act.

6. Given limited authorizations and our feeling that the number of procurement organizations should be limited, we see no need for the \$100,000 planning grants. At least for the first few years, designated procurement organizations should be restricted to those with the experience and economic stability to start without further planning assistance. The rest of the grant funds are ample to attract enough organizations for the program to provide nationwide coverage.

7. Section 376, the annual report, should be expanded to provide full disclosure of physician and institution specific comparative information covering utilization, price, and quality measures. Your determination that all information be made available to all "entities which are responsible for making payments for health care" is laudable.

Title II is the bridge between the promise of new technological discovery and the pain of rationing existing resources. In fact, the rationing of new procedures is not itself new, nor should we fear that this discussion represents a modern crack in the American character. The Stanford heart transplant program, the nation's largest and most successful, restricts its services to those who are less than 50 years old and without other major illnesses. Clearly, that is one of the primary reasons they report that 85% of their patients have returned to their full time work or avocation. From the origins of surgery, to the invention of the X-ray, to new drugs, to the latest high tech methods for preserving low-birth weight infants we have always faced lengthy periods of dissemination: periods in which some patients died awaiting treatment and others died as the treatments were being perfected. We have had liver transplants since 1963, pancreas since 1966, and heart transplants are now in their second decade. Only a fraction of those in need have been served. The difference today is that the debate is public, the promise so vast, the pain so visible.

Title II does not—nor should it—establish any entitlement to any organs or transplantation procedures. It does, appropriately in my view, require the Secretary to have a publicly articulated system for dealing with these emerging procedures.

There is concern that H.R. 4080 will stimulate more transplants and thus further escalation of medical care costs. There is also sentiment that perhaps government should stay out of this issue. The natural rationing done by medical institutions and the reimbursement process may be adequate. Both of these concerns are understandable, yet both are, I believe, flawed. Both represent a national desire to avoid making tough decisions, but that is the one choice we do not have. Demand and supply are on upward paths.

Currently, we suffer from very inconsistent policy. Government elects not to pay for experimental procedures, yet becomes an instrument for payment when a desperate mother can get on a televised Congressional hearing or command the public's heartstrings through the President's radio broadcast. The private sector responds the same way. Blue Cross and Blue Shield, in March 1983, reaffirmed their decision not to pay for liver transplants. However, between May 1981 and November 1982,

the Blues paid in full for 10 of the 36 liver transplants done at Children's Hospital in Pittsburgh.

The person in need, living donors, the next of kin of a deceased potential donor and the medical experts are all left in a state of confusion. Unless there is a large body of transplants, the process will remain classified as experimental and will also remain at a much higher than necessary price. Further, our assessment of what costs "too much" is as inconsistent as our reimbursement policy. We do not have national debates over the payment of multiple open heart procedures for the same patient. Yet, the Stanford heart team has reduced the cost of a heart transplant to only two times that of a normal open heart procedure. The success rate of pancreas transplants rose to 60 percent in 1983 which certainly places it on a par with many non-experimental but dangerous procedures.

We need to develop a publicly comprehensible approach to transplants. H.R. 4080 does not give that approach, it starts the process. The public needs to realize that there is only one way to avoid even more onerous rationing and the retention of high prices for transplantation: make more organs available. This is not a medical issue. It involves a complex matrix of culture, religion, legal definitions, and communications. As the debate progresses, we should at least carefully examine the "presumed consent" system supported by the Council of Europe. We could dramatically improve the identification and preservation of potential donor organs simply by requiring that the JCAH accreditation procedures stipulate that all hospitals have a donor organ plan. This does not mean all hospitals would do transplants, only that all would have a process for collecting and distributing those organs that may become available to their institution.

In short, if we want our citizens to have the advantage of transplantation, we must be willing to collect the organs, have a distribution system and pay a reasonable rate for the medical work done in regional centers. H.R. 4080 can help us cope with these issues.

Title II does restrict federal payment to those procedures which are done only in designated centers. This restriction is morally as well as fiscally appropriate and should be encouraged by similar agreements by all private payers. It is economically foolish to even consider encouraging the development of market forces stimulating the spread of community hospital based transplantation services. To do so would assure the spreading of poor quality medicine. The technology of transplantation requires comprehensive, multidisciplinary medical teams doing a large volume of procedures. The necessary volume and experience can come only from regionalization. For the patient, this is not a loss of freedom; it is a protection. For public and private payers, it is the only sensible way to manage payment while developing the data base upon which future policy decisions should be made.

CONCLUSION

In our view, the bill is consistent with the needed balance between competition and regulation. Regulation is needed to prohibit the sale and purchase of organs. By basing the selection of medical centers in which Medicare would pay for transplantation (or "other complex medical procedures") on criteria rather than past history, the bill fosters competition for excellence of procedure and health outcome.

A large societal question is whether we should, at a time when we are reducing our commitments to prevention and basic medical care, begin paying for esoteric procedures like transplants. In Medicare, that problem is acutely demonstrated. Medicare pays more than \$3200 per year for each beneficiary yet approximately 70 percent use less than \$400 worth of care. Moreover, approximately 28 percent of all Medicare dollars are expended during the last year of life of some six percent of the beneficiaries. H.R. 4080 cannot answer these questions but it does force the Secretary to formalize the process of integrating transplantation and other high tech services with the rest of our delivery systems. Hopefully, one result will be the establishment of a highly credible technology assessment system.

We are concerned that the research into the efficacy of these procedures, and of such new agents as Cyclosporin A, is not funded at a level which will provide clear policy guidance fast enough.

Transplantation, like regeneration and genetic engineering, is a breakthrough of such magnitude—with the potential for good and evil—that it is safe to say its broad application will not be deterred. The more traditional cycles of research may not be adequate for these very nontraditional developments. H.R. 4080 is not the place to determine what procedures should be called experimental, but it can help establish the process for these determinations in the future.

Further, as we use the definition of experimental to avoid paying for procedures it may be well to remember that we pay countless billions for the "treatment" of terminal illness; another 15-20 billion for defensive medicine in anticipation of malpractice suits, still more for iatrogenic results from inappropriate hospitalization and clinically unnecessary tests, and untold billions from just two products: tobacco and alcohol.

At the least, Congress should pass Title III and establish a program of technical assistance to facilitate all 50 state legislatures passing comparable intra-state prohibitions on the sale and purchase of human organs.

This country is the world leader not only in development of new medical technology but also in the commitment to make the best available to all. We must match that commitment with the resolve to squarely face the economically and ethically challenging issues raised by our growing capability in transportation. H.R. 4080 will make a positive contribution to this resolve and we in business, who not only pay the bill but also benefit from the new technology, applaud your initiative.

ARIZONA KIDNEY FOUNDATION,
PHOENIX, ARIZ., November 18, 1983.

Hon. JOHN MCCAIN,
U.S. House of Representatives,
Longworth Building, Washington, D.C.

DEAR MR. MCCAIN: The Arizona Kidney Foundation has actively assisted patients with end stage renal disease by providing direct financial support in the form of payments for medications, transportation, medical and hospital costs, house payments, utilities and food. The Arizona Kidney Foundation, recognizing the need for additional organs, has supported organ donation by aiding living donors through payments for costs incurred in travel to and from the transplant center, housing during testing, and other costs incurred while the donor is hospitalized or recovering.

The members of the Arizona Kidney Foundation are aware of pending legislation which may affect the Foundation's ability to continue to engage in such activities. The Arizona Kidney Foundation is a nonprofit corporation and, as organized, cannot and will not devote a substantial part of its activities to attempt to influence specific legislation. However, we believe it is appropriate to advise you of our nonpartisan analysis and study of proposed legislation and our views of what we would hope to see addressed in any legislation which may ultimately become law.

Reimbursement should be allowed for those costs associated with removal, storage and transplant of human organs. In addition, legislation should allow for individual and/or nonprofit organizations to cover reasonable costs of travel, housing, lost wages and other direct or indirect expenses incurred by a living donor and/or recipient.

The Arizona Kidney Foundation acknowledges there is a need for a national plan for organ acquisition and transplantation that addresses the needs of both potential recipients and possible living donors. We urge you, however, not to hastily develop a program which might undermine the current system or which might penalize either the recipient or the donor.

Sincerely yours,

JAMES F. PFENNING, *President.*

